IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| SECURITY POLICE AND FIRE PROFESSIONALS OF AMERICA RETIREMENT FUND, individually and on behalf of all other similarly situated stockholders,<br><br>Plaintiff,<br>-v.-<br><br>PFIZER, INC., as successor-in-interest to WYETH, a Delaware Corporation, ROBERT ESSNER, BERNARD POUSSOT, KENNETH J. MARTIN, and ROBERT R. RUFFOLO, JR.,<br><br>Defendants. | Civil Action No. 10-3105(SDW)(MCA) |

CONSOLIDATED AMENDED COMPLAINT

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1. Lead Plaintiffs, The City of Edinburgh Council as Administering Authority of the Lothian Pension Fund and Arca S.G.R. S.p.A. (collectively, "Lead Plaintiffs"), individually and on behalf of all other persons and entities who purchased Wyeth ("Wyeth" or the "Company") common stock between May 21, 2007 and July 29, 2008, inclusive (the "Class Period"), by their undersigned attorneys, allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Lead Plaintiffs' information and belief is based on their investigation (made by and through their attorneys), which included, *inter alia*, a review and analysis of: public documents pertaining to Wyeth and the Individual Defendants (defined below); Wyeth's filings with the Securities and Exchange Commission ("SEC"); press releases, earnings releases and public statements published by Wyeth and jointly published with Elan Corporation, plc ("Elan" and, together with Wyeth, the "Companies"); Wyeth press conferences, analyst conference calls, and the Company's website; analyst reports concerning the Company; newspaper and magazine articles (and other media coverage) regarding Wyeth, its business or the Individual Defendants; and confidential sources comprised of former employees of the Company.

## I. SUMMARY OF CLAIMS

2. This is a securities fraud class action brought on behalf of all persons and entities who purchased Wyeth common stock during the Class Period, asserting claims under the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t-1, 78t(a), and Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

3. This action alleges that Defendants (defined below) knowingly concealed material information and made false and misleading statements relating to Wyeth's most important pipeline drug, bapineuzumab, also known as AAB-001, which artificially inflated the price of Wyeth common stock during the Class Period.

4. During the Class Period, Wyeth was the world's fourth largest biotech and pharmaceutical company with annual sales of over $22 billion. Wyeth had partnered with Elan, an Irish neuroscience-based biotechnology company, to develop and test AAB-001 to treat patients with Alzheimer's disease. During 2006, the drug was in the midst of a "Phase II" clinical trial, designed to determine safety and efficacy. In October of 2006, while Phase II of the clinical trial was still underway, Wyeth announced that it (and Elan) planned to conduct an "interim review" of the Phase II study data (the "Phase II Interim Results") to determine if, "based on very specific criteria," the Phase II Interim Results warranted an early move to Phase III testing. Defendant Robert Ruffolo, Senior Vice President and President of Wyeth Research, publicly stated that the Phase II Interim Results would have to be "spectacular" in order for the Companies to move into Phase III testing.

5. On May 21, 2007, before the Phase II trial was complete, the Companies jointly announced that, based in part on the Phase II Interim Results, Phase III testing of AAB-001 would begin in the second half of 2007 (the "May 21, 2007 Announcement"). Based on their prior public statements, this represented that the Phase II Interim Results met the "very specific criteria" and were "spectacular."

6. In response to the May 21, 2007 Announcement of the move to Phase III, Wyeth's stock price jumped 4% on heavy trading volume of over 28 million shares to close at $58.41, ***a five year high***. The next day, Defendant Ruffolo, who had insisted that the Phase II interim results had to be "spectacular" to proceed to Phase III, exercised stock options and sold 130,436 Wyeth shares, netting over $2.35 million dollars in personal gains. On May 22, 2007, Wyeth's Chief Financial Officer ("CFO"), Defendant Martin, also exercised options and sold 200,500 Wyeth shares for a net gain of approximately $300,000. The timing of these trades, coming one

day after Defendants' materially false and misleading announcement concerning the move to Phase III trials, is highly suspicious.

7. Defendants did not disclose the actual results of the Phase II AAB-001 trial until more than one year later. Initially, on June 17, 2008, Wyeth and Elan issued a joint press release summarizing – *but not fully disclosing* – Phase II's purportedly "encouraging" results, and, for the first time, referencing – *and then downplaying* – the efficacy and safety concerns that the Phase II trial revealed. Left only with the Companies' spin on the results, the market remained bullish on AAB-001, and thus Wyeth's stock.

8. On July 29, 2008, after the close of the market, Defendants did disclose the full results of the Phase II trial. The full Phase II results revealed that AAB-001 had failed Phase II testing, and that Wyeth was able to tease out a positive spin on the study only by conducting post-hoc statistical analyses that departed from the original design and intent of the Phase II study. On the news that AAB-001 had completely failed the safety and efficacy parameters of the Phase II trial, Wyeth's stock price declined 11.9% in a single day (from $45.11 to $39.74, or $5.37) – *the largest single-day drop in six years of trading* – on extremely heavy volume of over 55 million shares. In one trading day, Wyeth's market capitalization declined by over $7 billion.

## II. PARTIES

### A. LEAD PLAINTIFFS

9. City of Edinburgh Council as Administering Authority of the Lothian Pension Fund ("Lothian") is one of the largest pension funds in the United Kingdom. As of March 31, 2010, Lothian had a fund value of £3.2 billion. Lothian purchased Wyeth common stock on the New York Stock Exchange ("NYSE") during the Class Period and was damaged thereby. By Order entered October 13, 2010, the Court appointed Lothian as a Lead Plaintiff in this action.

10. Arca S.G.R. S.pA. ("Arca") is a Milan-based institutional investor with over $26 billion in assets under management. Arca purchased Wyeth common stock on the NYSE during the Class Period and was damaged thereby. By Order entered October 13, 2010, the Court appointed Arca as a Lead Plaintiff in this action.

**B. DEFENDANTS**

11. Pfizer, Inc. (NYSE: PFE) is the world's largest pharmaceutical company, generating over $46 billion in annual revenues. Pfizer is a Delaware corporation headquartered in New York City, with its research headquarters in Groton, Connecticut, and local offices at 5 Giralda Farms, Madison, New Jersey. On January 26, 2009, Pfizer agreed to buy Wyeth for $68 billion, a deal financed with cash, shares and loans. The deal was completed on October 15, 2009, making Wyeth a wholly-owned subsidiary of Pfizer.

12. Wyeth, Inc. (formerly NYSE: WYE) had grown into the fourth largest biotech and pharmaceutical company with annual sales of $22.3 billion prior to its acquisition by Pfizer. Wyeth, which was called American Home Products Corporation from 1926 until March 2002, was organized as a Delaware corporation with its headquarters in Madison, New Jersey. Wyeth's primary Alzheimer's research facility was at all relevant times located in South Brunswick, New Jersey. Wyeth, now a wholly owned subsidiary of Pfizer, develops and markets traditional pharmaceuticals, vaccines, and biotechnology products that serve both human and animal health care.

13. Defendant Robert Essner ("Essner") was Chief Executive Officer ("CEO") of Wyeth from May 2001 through December 2007, and President from July 2000 until April 2006. Essner also was a Wyeth Director from 1997 to June 2008, and Chairman of Wyeth's Board of Directors from January 2003 to June 2008. Previously, Essner held the positions of Executive

Vice President of Wyeth from September 1997 to July 2000, and Chief Operating Officer ("COO") from July 2000 to May 2001.

14. Defendant Bernard J. Poussot, Jr. ("Poussot") was CEO of Wyeth from January 2008 through October 2009. He served as President from April 2006 to October 2009, and was COO from January 2007 through December 2007. Poussot was Vice Chairman of Wyeth's Board of Directors from April 2006 through December 2007, and was Chairman from June 27, 2008 until October 2009. From June 2002 to April 2006, he was Executive Vice President of Wyeth and President of Wyeth Pharmaceuticals, Inc.

15. Defendant Kenneth J. Martin ("Martin") joined Wyeth in 1984 and served as CFO and Vice Chairman from 2000 through June 2007. In 2000, he was also appointed Executive Vice President. Martin retired in June 2007.

16. Defendant Robert R. Ruffolo, Jr., Ph.D. ("Ruffolo") joined Wyeth in November 2000 and was President, Wyeth Research, and Senior Vice President, Wyeth, during the relevant period, until he retired in about May 2008. Ruffolo was responsible for all pharmaceutical research and development ("R&D") for the Company, including discovery, drug safety and metabolism, chemical and pharmaceutical development, clinical R&D and research operations.

17. Defendants Essner, Poussot, Martin, and Ruffolo are herein referred to as the "Individual Defendants." During the Class Period, the Individual Defendants, by virtue of their senior executive positions at Wyeth, were privy to confidential and proprietary information concerning Wyeth, its operations, finances, financial condition, and present and future business prospects relating to AAB-001. The Individual Defendants also had access to materially adverse non-public information concerning AAB-001 through their unfettered access to confidential corporate documents, conversations and connections with other corporate officers and employees,

attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided directly to them. Because of their possession of such information, the Individual Defendants knew that false statements were made or recklessly disregarded and that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

18. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to, and did, directly and indirectly, control the conduct of Wyeth's business and its market disclosures.

19. The Individual Defendants, because of their high-ranking positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases, and presentations to securities analysts and through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports, press releases, and analyst meeting materials alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

20. As senior executives and controlling persons of a publicly traded company whose common stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NYSE and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to Wyeth's financial

condition and performance; growth; operations; business; products; markets; management; earnings; and present and future business prospects, including all material information relating to the Company's most commercially important pipeline drug, AAB-001. The Individual Defendants also had a duty to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Wyeth's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

21. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Wyeth's common stock by disseminating materially false and misleading statements and/or concealing material adverse facts concerning AAB-001. The scheme: (i) deceived the investing public regarding the results of the Phase II AAB-001 trial, leading investors to believe that the results were "strong," "spectacular" and had met pre-specified criteria, when they were in fact abysmal, and the business, operations and management and intrinsic value of Wyeth's securities; and (ii) caused Plaintiffs and members of the Class to purchase Wyeth's common stock at artificially inflated prices, which declined dramatically when the truth was disclosed.

## III. JURISDICTION AND VENUE

22. The claims asserted herein arise under and pursuant to Sections 10(b), 20(a) and 20A of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t-1, 78t(a), and Rule 10-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

23. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act.

24. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). During the relevant period, Wyeth was headquartered in Madison, New

Jersey, and maintained research and manufacturing facilities in New Jersey, including its research facility relating to Alzheimer's disease in South Brunswick. The conduct complained of herein largely occurred in New Jersey, including the fact that most of the false and misleading statements emanated from New Jersey. During the relevant period, moreover, most Defendants lived and/or worked in New Jersey, and although Pfizer has since acquired Wyeth, it too maintains much of the laboratory and office space that Wyeth had in New Jersey, as well as continuing the substantial operations it had in New Jersey before acquiring Wyeth.

25. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

## IV. DEFENDANTS' FRAUDULENT SCHEME

26. Wyeth and the Individual Defendants' scheme involved the dissemination of materially false and misleading statements, and the concealment of material adverse information regarding the failure of the Phase II AAB-001 trial. Defendants knew, but failed to disclose, data demonstrating that AAB-001 did not outperform placebo throughout the Phase II study. Defendants also misled investors into believing that the Phase II interim results were "spectacular," "strong" and "very meaningful" when Defendants knew they were not, and concealed serious safety risks that had arisen during the Phase II trial, specifically that patients taking AAB-001 had disproportionately more adverse events than patients taking a placebo.

27. The scheme orchestrated by Defendants: (i) deceived the investing public regarding Wyeth's business, operations, management, and the intrinsic value of Wyeth's common stock; (ii) enabled Defendants to artificially inflate the price of Wyeth's common stock; (iii) enabled insider Defendants Ruffolo and Martin to sell over $2.6 million of their personally-held

Wyeth common stock while in possession of material adverse non-public information about the Company; and (iv) caused Lead Plaintiffs and other members of the Class to purchase Wyeth common stock at artificially-inflated prices, which – when the truth was revealed – caused purchasers of Wyeth common stock to suffer losses.

**A. BACKGROUND**

28. During the 1990s, Wyeth – which at the time was called American Home Products Corporation ("AHP") – began selling off the wide-ranging businesses it had acquired over the years in order to focus on pharmaceuticals. In March 2002, the Company changed its name from AHP to Wyeth. By the time of its acquisition by Pfizer, Wyeth had grown into the world's fourth largest biotech and pharmaceutical company with annual sales of $22.3 billion. It boasted that it was "one of the world's largest research driven pharmaceutical and health care product companies, with leading products in the areas of women's health care, infectious diseases, gastrointestinal health, central nervous system, inflammation, transplantation, oncology, vaccines and nutritional products." Wyeth marketed its products in more than 140 countries, and operated manufacturing facilities on five continents.

29. By 2007, Wyeth was best known in the prescription drug arena for manufacturing the gastrointestinal reflux disease treatment Protonix ($1.9 billion in annual sales) and the antidepressant Effexor (over $3 billion in annual sales). Effexor and Protonix accounted for over a quarter of Wyeth's sales in 2007. Wyeth's Effexor and Protonix patents were set to expire in 2010, but by early 2008 both were already under attack. In December 2007, well-known generics manufacturer Teva Pharmaceuticals, Inc. made an at-risk launch of generic Protonix, causing Wyeth's U.S. sales to drop by 58%. The patent on Effexor's active ingredient (venlafaxine) ran out in 2008 (with Wyeth still holding the patent on the extended release capsule form until much later) and Sun Pharmaceuticals, an Indian generics manufacturer, among several other generic

manufacturers, sought FDA approval for a generic version with the same active ingredient in tablet form. As a result of these generic threats, Wyeth's most important revenue streams were under severe pressure.

30. At the same time that Wyeth was struggling with these important patent issues, it was suffering significant losses on a number of other fronts. In 2007, Wyeth was just emerging battered from massive litigation relating to two of its ill-fated diet drugs, Redux and Pondimin (part of the "fen-phen" disaster of the late 1990s). That litigation had dragged on for a decade and cost Wyeth $21 billion. In addition, in 2007, Wyeth experienced widely publicized failures with New Drug Applications before the FDA. The FDA rejected Wyeth's osteoporosis drug, bazedoxifene, because of stroke and blood clot problems; rejected its schizophrenia drug, bifeprunox, because it was not as effective as other drugs on the market; and rejected its menopause drug, Pristiq, because of serious heart or liver complications experienced by clinical trial participants.

**B. ALZHEIMER'S DISEASE AND THE DESPERATE NEED FOR A CURE**

31. Alzheimer's disease is a progressive brain disease that slowly destroys memory and thinking skills, and eventually the ability to carry out even the simplest tasks. In most people with Alzheimer's, symptoms first appear after age 60. Alzheimer's disease is the most common cause of dementia among older people. Dementia is the loss of cognitive functioning –thinking, remembering, and reasoning – to such an extent that it interferes with a person's daily life and activities.

32. Alzheimer's disease is named after Dr. Alois Alzheimer. In 1906, Dr. Alzheimer examined the brain tissue of a woman who had died of an unusual mental illness, and found many abnormal clumps (now called amyloid plaques) and tangled bundles of fibers (now called neurofibrillary tangles). These plaques and tangles in the brain are two of the main features of

Alzheimer's disease. The third is the loss of connections between nerve cells (neurons) in the brain.

33. The cause of Alzheimer's disease is not known, but it is known that damage to the brain begins as many as 10 to 20 years before any problems manifest. It is likely that the causes include genetic, environmental, and lifestyle factors. Because people differ in their genetic make-up and lifestyle, the importance of these factors for preventing or delaying Alzheimer's differs from person to person. Tangles and plaques begin to develop deep in the brain and healthy neurons begin to work less efficiently. These neurons then lose their ability to function and communicate with each other, and eventually they die. This damaging process spreads throughout the brain, causing affected brain regions begin to shrink. By the final stage of Alzheimer's, damage is widespread and brain tissue has shrunk significantly.

34. Because Alzheimer's disease is a complex disease, scientists have struggled to find a cure. Current treatments are focused more on easing the debilitating symptoms of Alzheimer's. Four medications have been approved by the FDA to treat Alzheimer's. Donepezil (Aricept®), rivastigmine (Exelon®), and galantamine (Razadyne®) are used to treat mild to moderate Alzheimer's (donepezil can be used for severe Alzheimer's as well). Memantine (Namenda®) is used to treat moderate to severe Alzheimer's. These drugs work by regulating neurotransmitters (the chemicals that transmit messages between neurons). They may help maintain thinking, memory, and speaking skills, and help with certain behavioral problems, but the four approved drugs help only for a few months to a few years. None of these drugs have been shown to impact the underlying disease process.

35. Estimates vary, but experts suggest that as many as 5.1 million Americans and 26 million people worldwide have Alzheimer's. Alzheimer's is the fifth leading cause of death for

those over the age of 65. These numbers are growing, and as the "baby boomer" generation continues to age, the number of those affected by Alzheimer's disease could more than double. According to a report from the Alzheimer's Association, *Changing the Trajectory of Alzheimer's Disease: A National Imperative*, the need for a disease-modifying treatment has reached the point of a national crisis. Based on the current trajectory of the prevalence of Alzheimer's, the cumulative costs to care for those afflicted with the disease from 2010 to 2050 will exceed $20 trillion. Total annual costs of care for individuals with Alzheimer's disease by all payers is expected to soar from $172 billion in 2010 to more than $1 trillion in 2050, with Medicare costs increasing more than 600 percent, from $88 billion today to $627 billion in 2050.

36. Given the vast potential profits to be realized by the first company to discover a safe and effective disease-modifying Alzheimer's drug, several large pharmaceutical companies have invested hundreds of millions of dollars to try to bring an effective, FDA-approved Alzheimer's drug to market. Stock analysts, in turn, knowing the enormous potential of such a compound, track the results of Alzheimer's clinical trials very closely and factor their progress into their valuation models based upon the success or failure of the drug through the various stages of clinical development.

### C. THE DEVELOPMENT OF AAB-001 AND ITS EXTRAORDINARY POTENTIAL VALUE TO WYETH

37. In April 2000, Wyeth and Elan commenced a partnership to develop Alzheimer's drug therapies, focusing on compounds believed to represent a potential cure for Alzheimer's disease. They formed the Wyeth and Elan Alzheimer's Immunotherapy Program ("AIP"), which was a 50/50 collaboration to research, develop, and commercialize an immunotherapeutic approach to treat mild to moderate Alzheimer's disease and possibly prevent its onset.

38. AIP's research and clinical testing focused on what is known as "beta amyloid hypothesis," the proposition that aberrant protein clumps, or "amyloid plaques," in the brains of Alzheimer's patients are major causes of the disease. The hypothesis theorizes that breaking up or clearing these clumps from the brain with antibodies, such as AAB-001, would stave off dementia, prevent disease onset, and possibly lead to a vaccine or cure for Alzheimer's.

39. The AIP's first effort at developing an Alzheimer's drug targeted at breaking down amyloid plaques was the drug AN-1792, the predecessor to AAB-001. It was shelved due to toxicity concerns in January 2002 after 6% of patients in early Phase 2a testing developed a serious cerebral inflammatory response.

40. The "beta amyloid hypothesis" has never been proven and scientific critics cited in Forbes believe that the protein clumps are "either irrelevant or even possibly a defensive reaction by the brain tissue to the disease's neural assault." Nevertheless, developing a safe and effective amyloid inhibitor showed enough promise that drug companies (including, among others, Eli Lilly and Pfizer) have steadily pursued research, development, and testing.

41. Because AAB-001's mechanism of action was thought to attack the root cause of Alzheimer's, it was a potential first line treatment for all those presenting symptoms of the disease and was thought to be a potential "game changer." AAB-001 is a humanized monoclonal antibody delivered intravenously. It is thought to bind to and clear beta amyloid plaques in the brain. It is designed to provide antibodies to beta amyloid directly to the patient, rather than requiring patients to mount their own immune responses.

42. Data from Wyeth's small Phase I clinical study of AAB-001 presented and published in 2006 showed a slight, but statistically significant, improvement compared to placebo on a measure of cognitive function: the Mini-Mental State Examination. In February 2006, based

on the Phase I results and the significant unmet medical need of patients suffering from Alzheimer's, Wyeth sought and received from the FDA a "Fast Track" designation for AAB-001. AAB-001's Fast Track status meant that Wyeth was eligible for more frequent interaction and responsiveness from the FDA, including priority review and an acceleration of approval if further clinical testing showed promising results.

43. After the Phase I trials, Wyeth quickly began a Phase II clinical trial of AAB-001. Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteer patients.

44. The Phase II trial of AAB-001 was a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose study. It was conducted at 30 sites within the United States, and 234 patients were enrolled for an 18 month period starting in April 2005 and ending in March 2008. Patients were randomly assigned to placebo or AAB-001 in four dose cohorts (0.15, 0.5, 1.0, or 2.0 mg/kg). Patients received six infusions, 13 weeks apart, with final assessments at week 78. The pre-specified primary efficacy analysis assumed a linear decline of the intent-to-treat population, and compared, within dose cohorts, treatment differences between patients receiving AAB-001 and placebo using the Alzheimer's Disease Assessment Scale – Cognitive ("ADAS-cog") and Disability Assessment for Dimentia ("DAD") tests. Exploratory analyses combined dose cohorts and did not assume a specific pattern of decline.

45. When the development process for a new drug fails, it usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic or harmful effects. It is rare, therefore, for a drug company to move forward with Phase III testing absent a positive result in Phase II.

46. Phase III studies are randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at providing sufficient evidence of safety and efficacy to support FDA approval to market the drug. Typically, Phase III trials compare the drug to a placebo. With drugs that have Fast Track status, like AAB-001, it is common practice that Phase III trials will continue while the regulatory submission is pending at the appropriate regulatory agency. Thus, for drugs with Fast Track status, like AAB-001, a move to Phase III signals a path towards early approval of a drug.

47. Analyst and investor sentiment on Wyeth's intrinsic value and future potential was buoyed by the promise of AAB-001. Given the size of the largely untreated Alzheimer's population, the first safe and effective drug to combat the disease would command a hefty price premium, quickly generating billions of dollars in sales. By 2007, analysts at Decision Resources predicted that if the AAB-001 won approval, it would be an $8.8 billion drug by 2016, and would quickly become a drug generating $5 billion per year.

**D. THE PHASE II TRIAL AND "INTERIM REVIEW"**

48. Before the Phase II trial of AAB-001 commenced, Wyeth and Elan agreed that they would conduct an "interim review" of the preliminary Phase II results (the "Phase II Interim Results") before the study was complete, in order to determine whether and how to proceed to Phase III trials.

49. In October 2006, Wyeth publicly announced the planned interim review and the potential for an accelerated move to Phase III trials. Because proceeding to commence the Phase III trial before the Phase II trial was complete represented a rare and expensive move, Wyeth assured investors that they would move to Phase III trials if, and only if, the Phase II Interim Results met certain pre-specified criteria, including positive performance under the ADAS-cog and DAD tests for patients receiving AAB-001 as compared to patients receiving the placebo.

50. Thus, on October 5, 2006, Wyeth held its annual meeting for securities analysts (the first one it held since 2004). At this meeting, Defendant Ruffolo spoke about Wyeth's drug development program for Alzheimer's disease, and specifically about AAB-001, its development and prospects. He announced that Wyeth would conduct the Phase II Interim Results review and told investors that based on the results of the review, Wyeth would move to Phase III testing if those results were "spectacular." Specifically, Ruffolo stated:

> Now, again we don't have any results from this [Phase II] study at all, but we have a planned interim look at the data at the end of this year. And, based on this interim look, we could do two things. One, depending on the data, we could advance directly into Phase III in the first half of 2007, ***but the results would have to be spectacular.*** We don't know what results we're going to get. Alternatively, we could complete the study and then move to the next interim look, which would be in the first half of 2007. (emphasis added)

51. Wyeth (together with Elan) had established very specific criteria for defining success in the Phase II Interim Results review. The criteria included an assessment of the data using the ADAS-cog and DAD tests. Wyeth assigned a specific alpha error or "p-value" to assess the statistical significance of AAB-001's performance under the ADAS-cog and DAD tests at the interim review. If the data failed to meet Wyeth's predefined "p-value" under the ADAS-cog and DAD tests, Wyeth and Elan had agreed that they would not proceed to Phase III.

52. On January 9, 2007, Wyeth's partner in developing AAB-001, Elan, made a presentation at JP Morgan's 25th Annual Healthcare Conference in San Francisco, California. Elan's CEO (Kelly Martin) and its Executive Vice President and President of Global R&D (Lars Ekman) confirmed that Elan and Wyeth would perform an analysis of Phase II Interim Results, and provided additional details as to what Elan and Wyeth required to justify an early move to Phase III trials. Specifically, Elan's Martin and Ekman made the following statements to investors:

> **Elan's CEO Kelly Martin:** The Phase 2 trial, just to repeat what it is, it's a multiple ascending dose trial. There's 240 patients. There's another PET program, which has got 30 patients. We've got four different clinical endpoints to the trial, cognition, memory, quality of life and imaging. It's a very important trial.
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> And then, lastly, the important thing to emphasize is that ***Wyeth and ourselves have agreed*** to certain very specific criteria that need to be met in this Phase 2 trial in order to propel us into Phase 3.
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> What we've given the independent review group is very specific criteria that we're looking for. And we came up with that criteria by looking at a vast array of data, some of which I went through a little while ago that lets us anticipate which of these endpoints are going to move when and to what amplitude.
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> **Elan's Global Head of R&D Ekman:** We have defined a specific process by which we can in certain instances look at the data. As Kelly said, it's extremely controlled, because we have identified this trial as pivotal. That means we can't jump in and out of the data at our leisure, which you could if it was a non-pivotal Phase 2 study. We have also said that once we get positive data, we will inform the market. When you do these trials, it's a dose-escalation trial, so you start with the very low doses and then you move upward. And you start to look at the low doses at the shortest possible time and then you move upwards. And this is a trial that will continue through 2007 and during that time there will be interim looks. ***We have also jointly with Wyeth decided*** that we will not comment on when and how we're going to do the interim looks. We will inform the market when we have met the hurdles that we jointly set. ***And to paraphrase Bob Ruffolo, he said the data has to be – he used the word spectacular.*** I use the word it has to be strong, it has to be very meaningful. There are companies that decide to move into Phase III based on circumstantial evidence of efficacy, et cetera, but that's not the way we're going to operate. (emphasis added)

53. The statements by Defendant Ruffolo and Wyeth's partner Elan led the investing public to closely monitor Wyeth's actions with respect to both the look at Phase II Interim Results and the possible move to Phase III testing of AAB-001. Investors were told that a move to Phase III trials would occur only in the highly particularized circumstance that the Phase II Interim Results demonstrated that the study primary endpoints for safety and efficacy were being met. Further, the Companies publicly represented that the safety and efficacy measures seen during the

Phase II Interim Results review would have to be "spectacular," "strong," and "very meaningful," for the Companies to move into Phase III trials.

54. Based on Wyeth's and Elan's statements, analysts and investors understood that Wyeth would make the decision about whether and when to move to Phase III trials based upon the Phase II Interim Results review. Analysts and investors further understood that a move to Phase III trials meant that the preliminary data from Phase II was "spectacular," "strong" and "very meaningful," because that is what the Companies told them was necessary in order to justify an early move into Phase III trials of AAB-001.

55. For example, a November 8, 2006 analyst report published by Credit Suisse cautioned that waiting for the right entry point on Wyeth stock presented a risk since a positive disclosure of Phase II interim data "could be a meaningful catalyst," "may stimulate additional interest in the stock," and "may present an inflection point for the stock." According to the report, "significant positive results [from the Phase II interim look] would be a landscape-altering event in the development of Alzheimer's treatment."

56. Similarly, on February 20, 2007, Goodbody Stockbrokers published an analyst report which stated in part:

> On AAB-001, we are awaiting a second look at the data from patients currently on a Phase II trial. This will take place in mid-2007 and will determine whether or not a Phase III trial can be initiated before the current Phase II trial concludes. This is due in late 2007/early 2008. A positive outcome from the mid-2007 "look" would augur well for the drug.

### E. THE PHASE II INTERIM RESULTS WERE NOT SPECTACULAR, STRONG, OR VERY MEANINGFUL

57. Wyeth and Elan did conduct (or have conducted for them) the Phase II Interim Results review in the early part of 2007. The Phase II Interim Results did ***not*** meet the predefined "p-value" for the ADAS-cog and DAD tests and thus failed the interim review. Far from

"spectacular" or "strong," the Phase II Interim Results revealed both a lack of efficacy and serious safety problems with the AAB-001. According to a confidential witness (the "CW"), who was a former member of Wyeth's Neuroscience Steering Committee and Bapineuzumab Steering Committee, the Phase II Interim Results did not significantly differ from the Phase II final results, and neither one could be characterized as "spectacular" or "strong." Indeed, in the Phase II interim results, AAB-001 showed no "dose response," meaning higher doses of the drug were not associated with better results. Worse, in the total study population, statistical significance was not obtained on any of the pre-specified efficacy endpoints as measured by ADAS-cog and DAD, and was attained only in limited areas identified through post-hoc analysis. In other words, it was only after the Companies manipulated the data and changed the statistical analysis that any positive effect could be shown in a particular sub-group of patients.

58. With regard to safety, a large group of patients who were receiving AAB-001 suffered serious side effects, including increased ventricular volume, back pain, anxiety, vomiting, vasogenic edema, hypertension, weight loss, paranoia, skin laceration, gait disturbance, muscle spasm, cataract, deep vein thrombosis, syncope, seizures and pulmonary embolism. Three deaths occurred in the AAB-001-treated patient population compared to none in the placebo group. Thus, whatever slight benefits could be shown through the post-hoc manipulations of the Companies were, for the most part, overshadowed by the serious safety concerns that continued to plague AAB-001.

59. According to the CW, Defendant Ruffolo reported to Wyeth's R&D Committee that AAB-001 had failed to meet the established criteria for the Phase II Interim Results review. Nonetheless, Ruffolo further informed Wyeth's R&D Committee that Wyeth and Elan had decided to proceed to Phase III trials despite the failure of AAB-001 to achieve the very specific

criteria set by the Companies to define success in the Phase II Interim Results review. Numerous Wyeth executives expressed skepticism at this decision but Wyeth decided to proceed regardless.

60. Indeed, one of the CW's superiors showed him the Phase II Interim Results data during a private meeting shortly after the decision to move forward with Phase III testing was made by Defendant Ruffolo and others because he was "pissed off" that Wyeth, at the urging of Ruffolo, decided to proceed with a massive Phase III study. The Phase II Interim Results showed only circumstantial evidence of efficacy which, according to the CW, became "interesting" only when the population was divided into sub-groups according to whether the patient was a positive or negative carrier of the Apolipoprotein E4 ("ApoE4") gene. Additional Phase II testing of this sub-group, according to the CW, could be considered "interesting" and warranted further investigation, but only as a Phase II "exploratory" trial, not a large scale Phase III "confirmatory" trial. Indeed, according to the "Statistical Principles for Clinical Trials" issued by the U.S. Department of Health and Human Services in September 1998: "Any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted."

### F. WYETH MISLEADS THE PUBLIC THAT THE ABYSMAL PHASE II INTERIM RESULTS WERE "SPECTACULAR" AND "STRONG"

#### 1. The May 21, 2007 Announcement Was Materially False and Misleading

61. On May 21, 2007, the start of the proposed Class Period, Wyeth and Elan announced that they would be initiating Phase III clinical trials on AAB-001. Based on the Companies' prior statements, investors and analysts understood that Wyeth and Elan had conducted the interim look and that the Phase II Interim Results had met the predetermined criteria sufficient to proceed to Phase III trials.

62. Additionally, the May 21, 2007 Announcement explained that the Phase II study's key end-points were ADAS-Cog and DAD scores, thus strongly suggesting to the investing public, particularly given the context of the Companies prior statements on the subject, that the decision to move forward with Phase III trials was based on positive data on those critical end-points. Wyeth declined to reveal any specific information or data concerning the results of their Phase II Interim Results review. Instead, throughout the Class Period, Wyeth and its collaborators at Elan encouraged the investing public to believe that AAB-001 had satisfied the Companies' publicly-announced, stringent requirements for proceeding to Phase III clinical testing, including that the data seen from Phase II must have been "spectacular" and "strong."

**2. The Effect Of The Announcement On The Market**

63. Stock analysts attributed the move to Phase III testing as a representation that the data seen in the Phase II Interim review was "spectacular." For example, a Davy Research analyst report, published on May 21, 2007, stated as follows:

- Elan and Wyeth have taken a major step forward in the development of their lead Alzheimer's disease (AD) candidate, Bapineuzumab (AAB-001). The product will proceed to Phase III studies on an accelerated basis, 6-12 months ahead of the typical schedule.
- No data have been disclosed, *but both companies previously outlined that results from the Phase II interim analyses would need to be "spectacular" to proceed.*

64. On May 21 2007, *Reuters*' financial columnist Ben Hirschler published an article entitled "Hopes rise for Alzheimer's drug from Elan & Wyeth," in which he reported that "industry analysts said the decision to push ahead with late-stage testing suggested Elan and Wyeth had a promising new technology to tackle one of the world's most intractable diseases." Certain analysts, like Ian Hunter of Goodbody Stockbrokers, were quoted directly: "This is a very positive development for both Elan and Wyeth, given that the acceleration of the drug into a Phase

III study was only going to be considered if the interim data showed a significant improvement in patient progress." Hirschler also reported that analyst Corey Davis of Natexis Bleichroeder now believed that AAB-001 could be a "'bonanza' product, potentially selling as much as $13 billion if it were to reach 10 percent of U.S. Alzheimer's sufferers…." Further, according to analysts at NCB Stockbrokers, Hirschler reported that "[t]here is also a possibility it could be submitted for regulatory approval based on Phase II data alone, getting it to market earlier than investors expect."

65. *MarketWatch's* financial commentator, Sarah Turner, also chimed in. She wrote that "[t]he company's decision to start a Phase III trial before the results of the Phase II study are completely known implies that the Phase II results were positive." According to analyst Mike Ward at Nomura Code Securities, "The obvious inference is that if they're prepared to go into Phase III, then they believe that the Phase II data is sufficiently strong to go ahead." Ward also "noted that the start of Phase III trials is usually a milestone for drug companies, as it represents a point when they decide to commit more resources to developing the drug. It's also at this point that analysts begin to wonder if they should start to put the drug into sales and profit calculations."

66. Also on May 21, 2007, in an article published by the *Associated Press*, "Wyeth and Elan shares rise on plans for late stage study on Alzheimer's treatment candidate," Citigroup analyst Andrew Swanson was reported as concluding that "the decision to accelerate the [AAB-001 clinical study] program was taken from interim data of the Phase II study, which is still blinded." According to Swanson, "[i]f the product continues to clear its clinical development hurdles, it could be on the market by 2009, giving Elan and Wyeth a multiyear headstart on most other prominent Alzheimer's therapies in development and making [AAB-001] an almost certain blockbuster."

67. Cowen and Company analyst, Steve Scala, called AAB-001's move to Phase III "a clear positive" and confirmed that the "decision to advance [AAB-001] was made following a scheduled (May) interim look at the data from the Phase II trial. At the interim look, our consultants believe that Wyeth/Elan have a complete 18-month data set for those patients treated with the 0.5mg/kg dose of [AAB-001], and 18-month data on approximately half the patients treated with other doses being tested." Cowen and Company, for the first time, began to forecast 2011 and 2012 sales of the drug, assuming a positive result in Phase III trials.

68. Similarly, Credit Suisse disseminated a note to investors titled "WYE: Alzheimer's Drug Could Be Landscape Altering," in which Credit Suisse analysts concluded that "WYE's decision to start Phase 3 trials of [AAB-001] in 2H:2007 suggests the likelihood for upside from this program has increased significantly." Credit Suisse analysts found the market's reaction to the news to proceed with Phase III testing (which drove the stock price to a five year high) to be "insufficient" based on investors' "misunderstanding as to the implications of this." According to the Credit Suisse report, "[t]he company's interest in moving forward [to Phase III] implies that the drug has shown efficacy and reasonable safety at its lowest dose offerings," and so it was more probable than not that the drug would receive FDA approval since "the average probability of success is around 70% approval for drugs entering phase 3."

69. As part of the same reaction to the May 21, 2007 Announcement, a May 25, 2007 Goldman Sachs report stated "in our view, Bapineuzumab could potentially create a new paradigm for the treatment of Alzheimer's Disease; we view the supporting evidence for this approach as compelling."

70. As a direct result of the May 21, 2007 Announcement, Wyeth's stock price increased from $56.38 at close on Friday, May 18, 2007 to $58.41 at close on Monday, May 21,

2007 and $58.42 at close on Tuesday, May 22, 2007, a 3.6% climb. The stock price rise represented the belief by the market, perpetuated by the Companies' false and misleading statements, that the Phase II Interim Results must have been "spectacular," thereby creating an early pathway to approval and profitability of the AAB-001 Alzheimer's program.

71. On July 31, 2007, analysts at Natixis Bleichroeder published an analyst report reflecting the market's general understanding of the message the Companies' were communicating: "***We think the data at the interim look must have been profound and possibly involved a continual separation of drug from placebo over time – indicative of true disease modification.***" (emphasis added).

72. The market had so completely bought in to the perception created by the Companies that AAB-001 was successfully flying through clinical testing towards approval that, by April 2008, AAB-001 was the cover story on *Barrons*, with several financial analysts and investors quoted as espousing the belief that AAB-001 had the potential to be the most profitable drug of all time.

73. To the extent that any analysts and Wyeth investors harbored any doubts about the strength of the positive results that should be expected on the Phase II AAB-001 trial, such doubts were removed on May 1, 2008. On May 1, 2008, Wyeth's partner, Elan, through its CEO Kelly Martin, made a presentation to investors at the Morgan Stanley 2008 Global Healthcare Unplugged Conference in Miami, Florida. In his responses to investor questions regarding AAB-001, Elan's CEO not only continued to tout the strong results of Phase II, which according to him would be obvious to everyone who saw them, but suggested that they were *so strong as to create a "probable" path to early FDA approval*, as follows:

Unidentified Audience Member:

Hi, if I could just ask a Bapineuzumab question. You guys have talked about in the past that you would go into Phase III, only really on the basis of really clinically meaningful and even spectacular data and you've also indicated possibly being able to file sub par E on the Phase IIB data, the final data. I guess I'm trying to understand, what does that mean? Those qualitative descriptions. Does that mean we should expect statistical significance on Phase II? Does that mean we should expect trends? What exactly is spectacular?

Elan CEO Martin:

Spectacular is probably in the eyes of the beholder, but what we said before we moved into Phase III, that we would need to see clinically meaningful data. ***We have looked at with Wyeth and ourself - when I say we, Wyeth and ourselves, we looked at all the immunotherapeutic information, going back to the original IA in1792. Looking at the Phase I data, looking at the interim Phase II data, et cetera.*** When we took an interim look, we clearly were looking for some specific things from a clinical point of view. There was a number of end points that we were looking at. We looked at it at a period of time that was still fairly early on in the Phase II. So we both - we looked for both specific points and specific trends in certain things and we put that together and we had discussions with both the European agency and the U.S. agency, the collective decision was we should move to a Phase III, simultaneously.

We've kept the Phase II blinded because there is some chance, although again, as I've said to many people, it's not a high probability, but it is a probability. Or some probability, that the - if the Phase II data is really spectacular that there could be some regulatory pathway to a filing that would be earlier than a full normal completion of Phase III. That's going to depend, obviously on the data, its going to depend on discussions with the regulator etc. So what you should - what I believe that you should expect to see, what we would like you to see is that once you see the Phase II data, the marketplace and the investigators, the clinicians and everyone else who wants to look at it would say, ***geez, I understand exactly why Wyeth and Elan started a Phase III earlier than they did.*** I understand exactly why the Phase II remained blinded for the balance of the trial, and that from that you can draw your own conclusions from a confidence level about - based on the Phase III design, which is public and the Phase II data, you can put those two together and decide individually, collectively, the probability of having a drug and the pathway to having the drug, whether it's a combination two/three or three on its own will have to be determined with regulatory discussions.

* * *

Unidentified Audience Member:

So, just to be clear on the question of whether we should expect significance or not, understanding that this is a relatively small study and particularly at the interim it

was even smaller data set you had to look at. Would we expect significance in any one dose, would we expect significance in all three of the doses that you eventually took into Phase III. Would we expect significance on maybe a combined analysis of those three dosing cohorts or should we just not expect any kind of statistical significance and just pay attention to trends. How would we look at – how would you want us to look at it?

Elan CEO Martin:

I think it should be very obvious when we move to Phase III. So, without answering that specifically, I think it will be -- it should be obvious why we moved to Phase III and I think that whether its statistical significance in all or parts, supported by trends, or trends with different combinations of data points. I think that the reason we moved to Phase III was we clearly saw enough data to move forward. ***It's a huge decision for us, and for Wyeth and its one that we don't take lightly.*** And I also remind people that Elan has been working on immunotherapy for 20 years. So, as much pressure as there is to get to the last piece of information for the Phase II, we're not going to screw it up because we have a lot of other things in immunotherapy which we think are going to be relevant for years to come. So we are as anxious as anybody to look at the Phase II data, we've done a lot of work internally trying to predict what it would be. But our goal would be that as participants in the marketplace, that when you see the Phase II data, that there's unequivocal evidence why we moved to Phase III. Whether it's statistical in everything, some things or combinations of statistical plus trends, our goal would be that it would be very clear to all of you sort of why we moved to Phase III. . . . (emphasis added)

## V. FALSE AND MISLEADING STATEMENTS

74. Defendants made materially false and misleading statements throughout the Class Period in this action. Defendants misrepresented material facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts disclosed not misleading. The false and misleading statements generally fall into two categories: (a) false and misleading statements and material omissions representing that the results of AAB-001's Phase II clinical trials, including data seen by Defendants in the Phase II Interim Results review, were "spectacular," "strong," and/or "very meaningful," and (b) false and misleading statements and material omissions designed to deceive investors into believing that

AAB-001 was on the cusp of regulatory approval, based on the strength of Phase II data and the initiation of Phase III trials.

**A. THE MAY 21, 2007 ANNOUNCEMENT**

75. On May 21, 2007, Wyeth issued a press release entitled "Elan and Wyeth to Intitiate Phase 3 Clinical Trial of Bapineuzumab (AAB-001) in Alzheimer's Disease" (the "May 21, 2007 Announcement") – stating as follows:

> DUBLIN, Ireland & Madison, N.J -- May 21, 2007 -- Elan Corporation, plc (NYSE: ELN) and ***Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), today announced the decision to initiate a Phase 3 clinical program of their lead immunotherapeutic candidate, Bapineuzumab (AAB-001), for the treatment of patients with mild to moderate Alzheimer's Disease. This decision was based on the seriousness of the disease and the totality of what the companies have learned from their immunotherapy programs, including a scheduled Interim look at data from an ongoing Phase 2 study, which remains blinded.*** No conclusion about the Phase 2 study can be drawn until the study is completed and the final data are analyzed and released in 2008. Phase 3 clinical trial design will be finalized with regulatory agencies, and subject to regulatory approval, it is intended for the trial to begin in the second half of 2007. (emphasis added)

76. Defendants' May 21, 2007 Announcement was materially false and misleading when made because Defendants failed to disclose known, materially adverse information concerning the safety and efficacy results for AAB-001 in the Phase II trial, including:

a. The Phase II trial did not show "spectacular," "strong" and/or "very meaningful" results during the Phase II Interim Results review despite Defendants' statements that Phase III testing would commence only if such specific criteria relating to the predesigned efficacy and safety endpoints of Phase II trial were met.

b. The interim results, according to the CW, did not differ substantially from the Phase II final results which failed to show statistically significant results. "In the total study population, statistical significance was not obtained on the pre-specified efficacy endpoints of ADAS-cog and DAD." The trial was failing.

c. To the extent that the Phase II Interim Results demonstrated even circumstantial evidence of efficacy, it was because the Companies had engaged in post-hoc analyses of patient sub-groups designed to cast certain of the data in a more favorable light. FDA guidelines specifically reject such analyses as anything other than exploratory. Even with the benefit of post-hoc analyses, "no statistically significant changes were observed in any of the cognitive or functional efficacy endpoints."

d. In order to manufacture AAB-001's statistically significant performance against placebo in the Phase II trial, Defendants changed the statistical model *post hoc* from linear to curvilinear. This change was not disclosed. The original trial protocol called for linear modeling. Had Defendants not changed to curvilinear modeling without information investors, they could not have claimed that AAB-001 outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;

e. As Defendants later admitted, the Phase II trial showed no dose response, meaning that taking higher doses of AAB-001 did not correlate with greater improvement in symptoms;

f. The variability of the data seen in the Phase II Interim Results review, undisclosed to investors, suggested that any "result" could equally be due to chance as opposed to any positive impact of AAB-001, even in the ApoE4 non-carrier group; and,

g. Adverse events and serious safety problems were observed in a disproportionately high and statistically significant number of patients treated with AAB-001 as compared to patients receiving placebo.

77. In addition to this undisclosed material information related to the safety and efficacy of AAB-001 in the Phase II trial, Defendants also communicated to investors – through the commencement of the Phase III study – positive information that the Phase II study had met certain specific efficacy criteria. Defendants' failure to disclose that Wyeth would commence a Phase III clinical trial on AAB-001 notwithstanding the near total failure of Phase II testing further rendered the May 21, 2007 Announcement false and misleading, as the market had been told that Phase III would be initiated only upon meeting the criteria (spectacular Phase II endpoint results as measured by ADAS-cog and DAD tests). Additionally, as analysts confirmed, the market expected Phase III to serve as a "confirmatory" stage, and that drugs that enter Phase III are, by then, demonstrating a level of efficacy and safety that renders them highly (70%) likely to be approved, not, as here, subject to further "exploratory" testing designed to flesh out post-hoc theories.

**B. THE MAY 22, 2007 CITIGROUP HEALTHCARE CONFERENCE**

78. On May 22, 2007, Defendant Ruffolo spoke at the Citigroup Healthcare Conference (the "May 22, 2007 Conference"). He stated:

> Defendant Ruffolo:
>
> I know a number of you are going to have questions about our decision to move into Phase III in Alzheimer's disease with bapineuzumab, and I will tell you at the outset there is very little I am going to say. In fact, there is nothing I am going to say beyond the press release. And there are reasons for that. This is the press release -- the half portion of press release from two days ago or yesterday, indicating our reason for moving into Phase III. First off, the decision was based on a variety of factors, including the severity of the disease and everything we've learned from all of our immunotherapy programs, all the way from animal research up through our current clinical trials. The reason I am not going to discuss anything about our current Phase II clinical trial is because that is still an ongoing trial. It is the double-blind, placebo-controlled trial. It is in progress. And we cannot -- and I hope you'll understand, we cannot do anything to destroy the blind in that study. So I am not going to comment on the trial or anything about the trial.

> Q: Unidentified Audience Member ("UAM"): But clearly the one new piece of information is the interim Phase 2.. . . What was it -- what did you think you needed or I guess what did you need to see in the interim?
>
> A: Defendant Ruffolo: Yes, again, I cannot comment and will not comment on the interim look.. . .
>
> Q: UAM: One last question. So was the decision to go into Phase 3 made by somebody who knows whatever piece of information you are able to gain from that Phase 2 interim?
>
> A: Defendant Ruffolo: Again I am not going to comment on that either.. . .

79. Ruffolo's statements during the May 22, 2007 Conference were materially false and misleading when made because, he knew, but did not disclose (a) of the safety and efficacy problems plaguing Phase II; (b) that the Phase II Interim Results did not meet the pre-established criteria for moving to Phase III and were not, among other things, "spectacular" and (c) that AAB-001 had serious issues with respect to safety and efficacy that would give it a very small chance of success in the Phase III trial.

80. Wyeth's stock increased from $56.38 at close on Friday, May 18, 2007 to $58.41 at close on Monday, May 21, 2007 and $58.42 at close on Tuesday, May 22, 2007, a 3.6% climb. This statistically significant price increase took place despite a broader pharmaceutical industry *decline* of -0.69%. With Wyeth's stock trading at or near its 5-year high on May 22, 2007, Defendant Ruffolo exercised options and sold Wyeth shares to realize a net personal gain of over $2.3 million.

### C. WYETH'S 2Q 2007 EARNINGS CALL (JULY 19, 2007)

81. On July 19, 2007, Wyeth convened analysts and investors for its 2Q 2007 earnings conference call – its first since the 5/21/2007 Announcement. During the call, the following exchange occurred:

> David Risinger (Merrill Lynch Analyst):
>
> Thanks very much. ***Could you comment on the move of bapineuzumab into Phase 3, please? I believe that Dr. Ruffolo said last year that the interim results would have to be spectacular to move the product into Phase 3 based on the interim look. So if could provide some color on that, that would be helpful…..***
>
> Justin Victoria (Wyeth Investor Relations):
>
> David, this is Justin. Regarding your inquiry on the bapineuzumab interim analysis of the Phase 2 results, ***the Phase 2 study remains blinded and continuing and clearly our interim analysis of the Phase 2 results was a component in the decision that we and Elan reached in terms of moving into Phase 3*** or preparing to move into Phase 3. But it was as we indicated in our press release. It truly was a composite of all of the information that we have at hand, the interim analysis of the Phase 2 results; the Phase 1 results that were presented last year; the earlier work with the first formulation in the beta amyloid family, the AN-1792; our understanding of the mechanisms; the need for new therapies, effective new therapies and the condition. ***So it really was a composite and not just the Phase 2 results, spectacular or otherwise.*** (emphasis added)

82. The foregoing statements were false and misleading. The statements by Justin Victoria ("Victoria") in response to a direct question about whether the Phase II Interim Results were "spectacular" were false and misleading. Victoria confirmed that "clearly our interim analysis of the Phase 2 results was a component in the decision….in terms of moving into Phase 3," while concealing the fact that the Phase II Interim Results demonstrated little, if any, efficacy and showed serious safety issues with AAB-001. Moreover, Victoria's statement referencing the Phase II results as "spectacular or otherwise" was misleading because it falsely denied knowledge as to whether the Phase II results were or were not spectacular when, in fact, Defendants knew that the results were not spectacular and had not met the criteria set by Wyeth to define success during the Phase II Interim Results review.

### D. JANUARY 8, 2008 JP MORGAN HEALTHCARE CONFERENCE

83. On January 8, 2008, Wyeth attended a JP Morgan Healthcare Conference and spoke to analysts and investors. At the conference, Joseph S. Camardo, M.D., Wyeth's Senior Vice President, Global Medical Affairs, made the following statements:

> ***I want to talk to you a little bit about bapineuzumab***. I made the point with Enbrel and Prevnar that technology with substantial medical impact is really what we need for growth in our business. All of us do. ***This product could be the breakthrough the world needs for Alzheimer's Disease.*** And that's why we are investing in it along with our partner, Elan. This drug is not a copy, it's not going to be an incremental symptomatic improvement. If it works, it's going to be a huge leap, the kind of leap that Enbrel made, that Prevnar made and even that Effexor made back in the mid-'90s. Now we won't know this until the studies are finished. We'll have our Phase II released in the middle of 2008. But we have already started our Phase III program with four studies in over 4,000 patients. So we believe in it. ***We learned a lot in Phase II. And one thing we learned is that the ApoE4 gene pre-disposes patients to something called vasogenic edema. So we are taking care of that in Phase III by stratifying the patients and giving different doses based on the presence or absence of this gene. It's a big insight. We have co-primary efficacy endpoints, validated cognitive and functional scales, and most important, and this is really critical, we have agreed on all the endpoints with all the authorities who will ultimately have to approve this product. So what I am saying is all the background work, all the planning is done. The only risk is whether the drug is safe and effective, but that's always the risk in R&D.*** Now what we are doing is executing our program and we'll evaluate the results. (emphasis added)

84. Camardo's statements were false and misleading. While Camardo stated that "Wyeth learned a lot in Phase II," and specified some of the "things" that the Company learned, he did not disclose that Wyeth had learned other, negative things about AAB-001, specifically that the drug had serious safety and efficacy issues when compared to placebo. In addition, these statements were false and misleading because AAB-001 was moved into Phase III trials *despite* its near total failure in Phase II testing, which Defendants knew on account of their Phase II Interim Results review. Further, the statements were false and misleading because the Phase II Interim Results review confirmed that AAB-001 was still plagued by serious safety issues that overwhelmed any slight efficacy advantage that could be teased from the Phase II data.

Therefore, far from being truly "the breakthrough the world needs for Alzheimer's Disease," with a "huge possibility for growth," AAB-001 was another Alzheimer's compound that was failing in clinical testing.

**E. THE MARCH 19, 2008 LEHMAN BROTHERS GLOBAL HEALTHCARE CONFERENCE**

85. On March 19, 2008, Wyeth again presented to analysts and investors convened for the Lehman Brothers Global Healthcare Conference. Wyeth's Senior Vice President, Joseph M. Mahady ("Mahady") made the following statements:

Mahady:

> The other things I will highlight for you here are bapineuzumab, which we are looking forward to not only the start of our Phase III trials, which really have just began at the end of '07; more importantly we look forward to the final results of the Phase II study becoming available some time in June of this year.
>
> * * *
>
> Our R&D capability really remains strong in the three basic technology platforms of vaccines, small molecules and protein products, and really believe that that pipeline offers us near-term opportunities and some -- such as bapineuzumab -- which really offer us kind of near and mid-term opportunities for transformational growth for the company.

86. Mahady's statements were false and misleading because, in context, he was deliberately misleading the market to believe that AAB-001 was one of the products in Wyeth's pipeline that offered "near and mid-term opportunities for transformational growth of the company," despite the fact that by this point in time Wyeth and Mahady were privy to enough of the Phase II results to know that the study was negative, and that AAB-001 would not be a positive catalyst for the Company. In addition, these statements were false and misleading because AAB-001 was moved into Phase III trials *despite* its near total failure in Phase II testing, which Defendants knew on account of their Phase II Interim Results review. Further, the statements were false and misleading because the Phase II Interim Results review confirmed that

AAB-001 was still plagued by serious safety issues that overwhelmed any slight efficacy advantage that could be teased from the Phase II data. Therefore, far from presenting investors with "near and mid-term opportunities for transformational growth of the company," AAB-001 was another Alzheimer's compound that was failing in clinical testing.

**F. WYETH'S 1Q 2008 EARNINGS CALL (APRIL 22, 2008)**

87. On April 22, 2008, Wyeth held an earnings conference call with analysts and investors to discuss its first quarter results (the "April 22, 2008 Conference Call"). During the call, Defendant Poussot stated as follows:

> We'll remind you that Alzheimer's disease is a complex and formidable challenge and our research programs contain inherent risks. ***Wyeth and Elan made the decision to begin our Phase III program late last year with the support of regulatory authorities, and based on a composite of the following information. First, the interim review of data from this Phase II study last year;*** second, information learned from our other immunotherapy programs; and third, the absence of effective treatments for this terrible disease. ***Wyeth, Elan, the medical community and you, we all are looking forward to the full final Phase II analysis to be completed and announced by mid-year.***

88. Also during the April 22, 2008 Conference Call, Wyeth's Victoria had the following exchange with an analyst from Morgan Stanley:

> Jami Rubin (Morgan Stanley Analyst):
>
> Justin, maybe you could frame for us potential outcomes for the Phase 2 data in bapineuzumab. As you earlier said, it's a small trial. Typically you don't look for or expect to see statistical significance. This is unusual in that you decided to move into Phase 3 without completing the full Phase 2. If you could frame for us what the potential outcomes are for Phase 2. Will we see signs of disease modification. Is it efficacy we're looking for? Is it the safety profile? Whatever color you could provide in terms of scenarios would be appreciated.
>
> Victoria:
>
> ***The Phase 2 study as I said, it's designed to evaluate the safety of the product and give us direction in terms of dose and certainly we're looking for signals of effect of the drug. But how robust those signals are going to be is what we're going to find when we do the analysis of the Phase 2. The purpose there is to inform our decisions to go forward into Phase 3. As Bernard noted, one of the***

> ***key aspects for the decision to go forward into Phase 3 was the interim analysis of the Phase 2 study that was conducted in the mid-part of last year, in 2007,*** but we also took in to account all of the information, that we had gleaned from our immunotherapy program with Elan over the years including AN 1792, the Phase I results from AAB and all of the pre-clinical work that substantiated the beta amyloid hypothesis. And that in conjunction with the very significant unmet medical need of Alzheimer's led us to Elan working with the regulators to endorse the initiation of the Phase III at late last year. . . . (emphasis added)

89. These statements were false and misleading. While stating that the decision to move to Phase III trials on AAB-001 was based on the interim review of the Phase II trial, Poussot and Victoria omitted to state that the interim results were negative and did not support the move to Phase III under the Companies own pre-defined criteria. These statements were also false and misleading because AAB-001 was moved into Phase III testing *despite* its near total failure in Phase II testing, which Defendants knew on account of their Phase II Interim Results review. Further, Defendant Poussot's and Victoria's statements were false and misleading because the Phase II Interim Results review confirmed that AAB-001 was still plagued by serious safety issues that overwhelmed any slight efficacy advantage that could be teased from the Phase II data. Thus, despite falsely stating otherwise, Victoria knew there was no potentially "robust" signal from Phase II testing that supported Wyeth's move to Phase III trials, particularly given the "very specific criteria" disclosed to the market to justify such a move.

### G. THE JUNE 17, 2008 PRESS RELEASE OF PHASE II TOP-LINE DATA

90. On June 17, 2008, Wyeth and Elan jointly issued a Press Release entitled "Elan and Wyeth Announce Encouraging Top-line Results from Phase 2 Clinical Trial of Bapineuzumab for Alzheimer's Disease" announcing only the top-line results of Phase II (the "June 17, 2008 Announcement"). The June 17, 2008 Announcement stated:

> Elan Corporation, plc . . . and Wyeth . . . today announced encouraging preliminary findings from a Phase 2 study of bapineuzumab (AAB−001) in patients with mild to moderate Alzheimer's disease. In the 18−month trial, bapineuzumab appeared to have clinical activity in treating Alzheimer's disease.

Efficacy Findings
The study did not attain statistical significance on the primary efficacy endpoints in the overall study population. Post−hoc analyses did show statistically significant and clinically meaningful benefits in important subgroups. In non−carriers of the Apolipoprotein E4 (ApoE4) allele, estimated in the literature to be from 40 to 70 percent of the Alzheimer's disease population, post−hoc analyses showed statistically significant and clinically meaningful benefits associated with bapineuzumab treatment on several key efficacy endpoints, including the Alzheimer's Disease Assessment Scale (ADAS−cog), the Neuropsychological Test Battery (NTB), the Mini Mental State Examination (MMSE) and the Clinical Dementia Rating – Sum of Boxes (CDR−SB). A favorable directional change was seen on the Disability Assessment Scale for Dementia (DAD), although this was not statistically significant.

* * *

Safety Findings
As expected given the nature of the population studied, adverse events were very common in both placebo and bapineuzumab−treated patients. In non−carriers, the number of patients experiencing serious adverse events was similar between placebo and bapineuzumab−treated patients. In carriers, serious adverse events were more frequently observed in bapineuzumab−treated patients than in placebo patients. In addition, vasogenic edema was reported in the treated population with an increased frequency in carriers and at higher doses. No cases were reported in placebo patients. In the ongoing Phase 3 studies, carriers of the ApoE4 allele are being treated with a lower dose to minimize the risk of vasogenic edema. The Companies believe that the overall safety findings from this Phase 2 trial support their prior decision to move to Phase 3 studies.

CEO Comments
"The preliminary analyses of the Phase 2 study are a continued validation of the amyloid approach to Alzheimer's disease and an important milestone in our companies' ongoing commitment to bring new treatment options to patients," said Kelly Martin, President and CEO of Elan. "These results clinically support our decision to move into Phase 3 last year."

* * *

These findings reflect preliminary analyses of the Phase 2 data and its implications for ongoing clinical development of bapineuzumab. In this trial, there were imbalances in patient numbers and characteristics at baseline between subgroups studied that may or may not have affected these results.

91. The statements contained in the June 17, 2008 Announcement were materially false and misleading when made because they failed to disclose the full truth concerning the Phase

II Interim Results and the Phase II Final Results. For example, although the June 17, 2008 Announcement referenced vasogenic edema, it failed to disclose its prevalence among the study population ***or the fact that it was just one of dozens of serious problems experienced by AAB-001 recipients.*** And, although the June 17, 2008 Announcement referenced certain efficacy shortcomings, it failed to adequately disclose the manipulative manner in which the slight efficacy advantage in ApoE4 non-carriers was achieved, or the fact that even this slight efficacy advantage might be completely invalid (and due to chance) on account of the extreme variability seen in the data. The release did not disclose the overwhelming percentage of patients that AAB-001 did not help, the variability and randomness of the data, or the complete lack of dose response. The Company improperly used the pre-announcement of results to bolster prior falsities and to continue to artificially inflate the stock price.

### H. THE 2Q 2008 EARNINGS REPORT ON FORM 8-K AND EARNINGS CONFERENCE CALL (JULY 23, 2008)

92. On July 23, 2008, Wyeth pre-released its second quarter earnings report on Form 8-K (the "July 23, 2008 8-K"), and held an investor conference call to discuss the results the same day (the "July 23, 2008 Conference Call"). Defendant Pousott discussed Phase II of the AAB-001 trials in both, stating, "we are encouraged by the Phase 2 results for bapineuzumab in Alzheimer's disease that support our decision to initiate Phase 3 trials" in the July 23, 2008 8-K, and, "As stated before, these results are encouraging and supportive of our prior decision to initiate Phase 3" during the July 23, 2008 Conference Call.

93. Poussot's statements in the July 23, 2008 8-K and during the July 23, 2008 Conference Call were materially false and misleading when made because, despite knowing (a) of the safety and efficacy problems plaguing Phase II; (b) that the market had been specifically told that a move to Phase III meant that the Phase II Interim Results met specific criteria and were,

among other things, "spectacular" and (c) that the market considered drugs entering Phase III to have demonstrated a high level of safety and efficacy in Phase II such that, on average, 70% of Phase III drugs are approved, Poussot actively touted the Phase II Interim and final results and refused to properly inform the market of the true negative state of the Phase II Interim and final results.

## I. THE TRUTH ABOUT PHASE II RESULTS IS REVEALED

94. On July 29, 2008, the last day of the Class Period, Wyeth and Elan jointly issued a press release entitled "Elan and Wyeth Present Encouraging Results from Phase 2 Clinical Trial of Bapineuzumab at International Conference on Alzheimer's Disease" announcing the final results of Phase 2 (the "July 29, 2008 Announcement"). The July 29, 2008 Announcement stated:

> The study did not attain statistical significance on the pre−specified efficacy endpoints in the overall study population. Post−hoc analyses showed statistically significant and clinically meaningful benefits in important subgroups.
>
> * * *
>
> Pre−Specified Efficacy Analysis:
> In the total study population, statistical significance was not obtained on the pre−specified efficacy endpoints of ADAS−cog and DAD.
>
> * * *
>
> The study revealed important differences in the rate of vasogenic edema by carrier status and for this reason the total population was analyzed by ApoE4 carrier status
>
> * * *
>
> ApoE4 Carrier Population
> In the ApoE4 carrier patients, no statistically significant changes were observed in any of the cognitive or functional efficacy endpoints. The completer analysis for the carrier population showed favorable directional changes on cognitive and functional endpoints. The ongoing Phase 3 studies in ApoE4 carriers will help clarify these findings.
>
> MRI findings in the carrier patients showed no significant change in brain volume between bapineuzumab treated and placebo patients, while a significant increase in ventricular volume in treated patients was observed, mean 2.5cc; p=0.037. The clinical relevance of this finding is still unclear and will continue to be evaluated.

* * *

Safety Findings
Adverse Events (AE) were observed in 95% of bapineuzumab treated patients versus 90% of placebo treated patients. AEs were generally mild to moderate and transient. With the exception of vasogenic edema, AEs did not appear to be dose related.

Adverse events seen in greater than 5% of bapineuzumab treated patients and at twice the rate of placebo treated patients were: back pain; anxiety; vomiting; vasogenic edema; hypertension; weight loss; paranoia; skin laceration; gait disturbance; and muscle spasm.

Three deaths occurred in bapineuzumab−treated patients, though these were not considered by the investigators to be treatment related. No deaths were reported in the placebo group. Other adverse events of interest occurring in less than five percent of patients treated with bapineuzumab included cataract, deep vein thrombosis, syncope, seizures and pulmonary embolism.

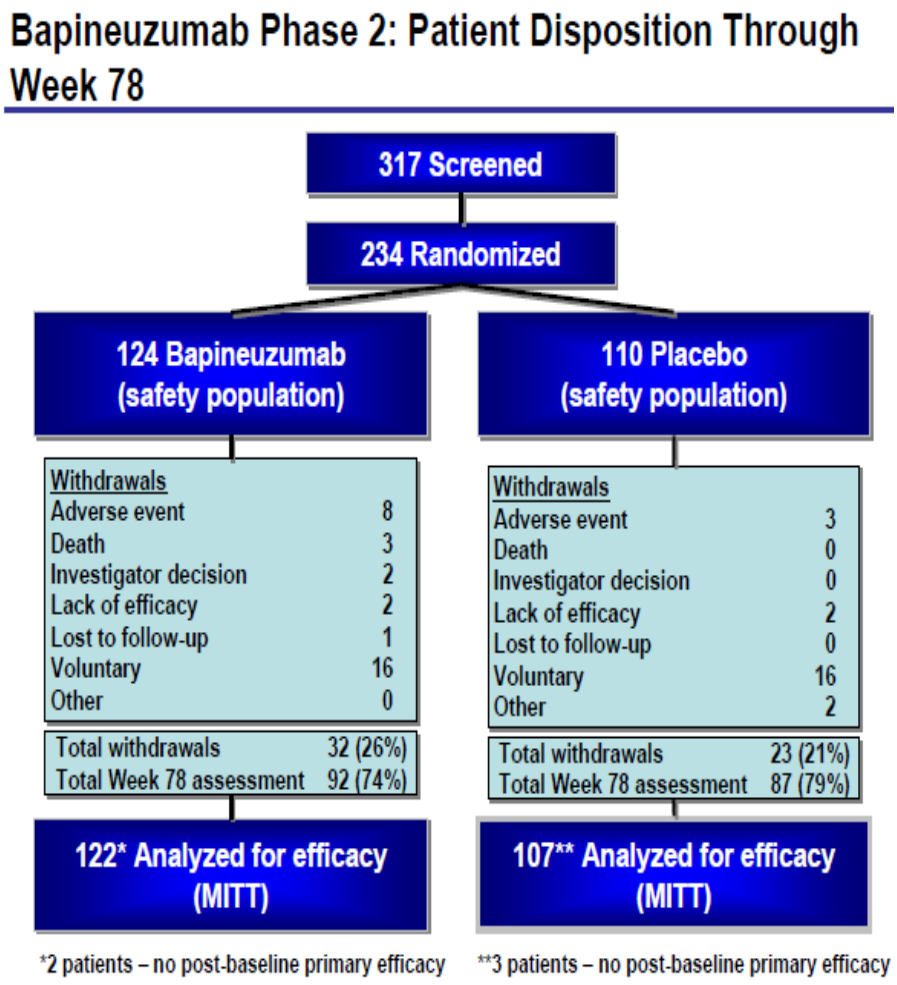
Vasogenic Edema (VE)
Twelve (12) cases of vasogenic edema were reported, all in treated patients, and all resolved over time. Ten (10) of these cases were reported in ApoE4 carriers with 2 cases in ApoE4 non−carriers. Eight (8) of the 12 cases were reported in the highest dose group, including both cases seen in ApoE4 non−carriers. Six (6) of the 12 cases were not associated with clinical symptoms and were detected on routine MRI scan. One (1) patient was treated with steroids. Re−dosing was instituted in six (6) of the 12 patients and no recurrence of VE was observed.

Phase 3 Program Implications The Phase 2 data reinforce the design of the ongoing Phase 3 studies by ApoE4 carrier and non−carrier populations and the selected dose groups. The companies plan to continue all four ongoing Phase 3 studies. The ApoE4 carrier dose in the Phase 3 trials was selected to seek to minimize the risk of VE observed in the Phase

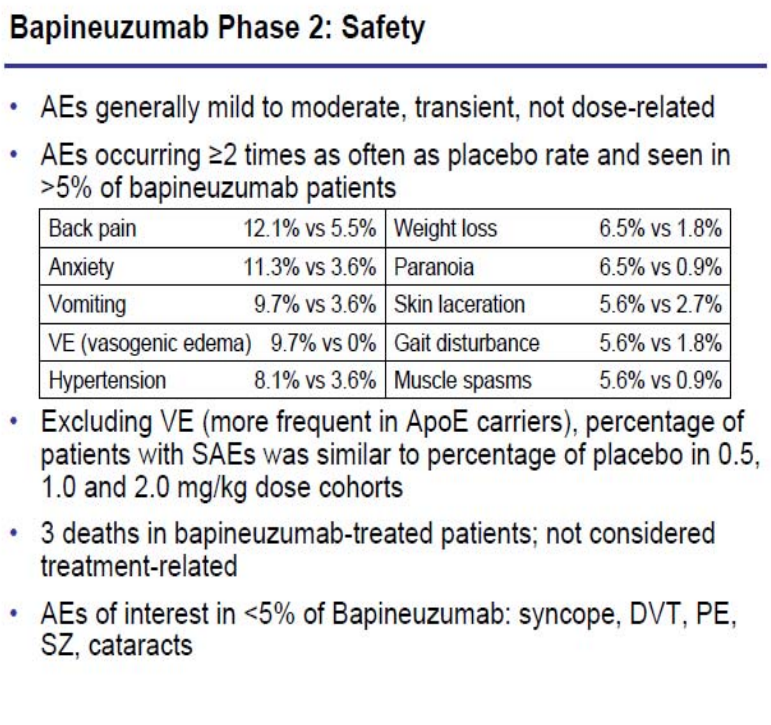
95. Defendants expanded on the July 29, 2008 Announcement later the same day (and after the market close) at the International Conference on Alzheimer's Disease ("ICAD"), during which they further explained the data, methods of analyses, and difficulties encountered during Phase II trials of AAB-001. The presentation at ICAD was a disaster. After more than a month of speculation following the release of top-line preliminary results, researchers, physicians, members of the press, and Wall Street turned out in droves to see the final (and full) presentation of the Phase II results.

96. The efficacy data was weak, at best, and the safety data was worse than the Company had previously disclosed. The following slides from Defendants' ICAD presentation, for example, illustrate some of the serious safety problems encountered during Phase II:

**Defendants' ICAD Presentation Slide 5**



**Defendants' ICAD Presentation Slide 7**



**Bapineuzumab Phase 2: Safety**

- AEs generally mild to moderate, transient, not dose-related
- AEs occurring ≥2 times as often as placebo rate and seen in >5% of bapineuzumab patients

| | | | |
|---|---|---|---|
| Back pain | 12.1% vs 5.5% | Weight loss | 6.5% vs 1.8% |
| Anxiety | 11.3% vs 3.6% | Paranoia | 6.5% vs 0.9% |
| Vomiting | 9.7% vs 3.6% | Skin laceration | 5.6% vs 2.7% |
| VE (vasogenic edema) | 9.7% vs 0% | Gait disturbance | 5.6% vs 1.8% |
| Hypertension | 8.1% vs 3.6% | Muscle spasms | 5.6% vs 0.9% |

- Excluding VE (more frequent in ApoE carriers), percentage of patients with SAEs was similar to percentage of placebo in 0.5, 1.0 and 2.0 mg/kg dose cohorts
- 3 deaths in bapineuzumab-treated patients; not considered treatment-related
- AEs of interest in <5% of Bapineuzumab: syncope, DVT, PE, SZ, cataracts

7

97. According to Adam Feuerstein, Biotech analyst for *the TheStreet.com*, the data was "weak," "underwhelming," and "inconclusive." He wrote:

> The phase II study failed its primary endpoint rather convincingly. Patients treated with [AAB-001] showed no improvement in either cognition of function compared to placebo.
>
> So, what did Elan and Wyeth do with these negative results? They essentially threw them out and rewrote the rules of the study in order to find groups of patients who responded. First, the two companies changed the statistical analysis plan. Second, they broke down and analyzed the data for efficacy based on a post-hoc subgroup comparing patients who are carriers and non-carriers of the ApoE4 gene, a genetic variant that increases a person's risk for developing Alzheimer's.
>
> Not content with one retrospective analysis, Elan and Wyeth went a step further. They also re-analyzed the results using a so-called "completers analysis" that only included patients who received the full complement of bapineuzumab injections. Such extensive data-mining as this totally erodes any confidence that the "positive"

> findings being shown can be replicated in the ongoing phase III studies. There is way more risk in the bapineuzumab program now, which is why the stocks sold off so hard.

98. Feuerstein also pointed out that the data was "wildly inconsistent" with what was presented as the top-line results in June, stating that "[t]here was absolutely no dose response with [AAB-001] in this trial. Typically, you like to see increasingly higher doses of a drug correspond with improved efficacy. Instead, what we saw from the [AAB-001] study just looked like so much randomness, which in clinical trials is definitely not a good thing. The lowest doses of the drug worked better on some measures of cognition and function, while higher doses worked better on others. Sometimes, doses in the middle produced worse results than placebo."

99. Feuerstein also found that the supposedly positive efficacy spin the Companies put out relating to the ApoE4 non-carrier group of patients was the result of Wyeth and Elan post-hoc data torturing, rather than representing a real result:

> The ApoE4 non-carrier group of patients was Elan and Wyeth's best shot at making a convincing case for [AAB-001], but once again, the details in the data Tuesday -- stuff not available in June -- tripped them up. For starters, there was an imbalance in the baseline mental status of patients in the [AAB-001] and placebo arms that could have skewed the results in favor of the drug. When you look at the actual performance curves of the study, [AAB-001]-treated patients reported a 5-point improvement over placebo on the ADAS-cog test, a measure of cognition and a co-primary endpoint of the study. However, for nearly a year into the 18-month trial, the [AAB-001] and placebo patients were both losing cognition at the same rate. The benefit seen for [AAB-001] patients only came about because placebo patients suffered a steep loss of cognition at the very end of the study.
>
> * * *
>
> The loss of cognition by placebo patients totaled 11 points on the ADAS-cog scale at 18 months, far worse than is typically seen in other Alzheimer's studies of this duration.… The concern here is that the improvement in cognitive function seen in the ApoE4 non-carriers is not a result of anything that [AAB-001] is doing, but is instead caused by poor-performing placebo patients from a small subset analysis. The Companies tried to hide these data-mining shenanigans by analyzing the data using an unusual statistical technique that departed from the originally-planned intent-to-treat protocols. Instead of using a slope analysis, which shows how the patients do at every time point, to a different analysis called "MITT repeated measures model without assumption of linearity." This technique essentially

> compares baseline to the final assessment at 78 week / 19.5 months, and incorporates time points in between in ways that are not directionally shown. This technique masked and obfuscated the unusually sharp decline of the placebo patients, allowing the Companies to tease out a slight showing of statistical significance in the ApoE4 non-carrier sub-group only.

100. Gabrielle Strobel, Managing Editor of the Alzheimer Research Forum, and former science writer at Harvard Medical School, reported that scientists attending the ICAD presentation of Phase II results "felt that the presentation could have been more straightforward" and she found that "many listeners did not buy [the Companies spin on efficacy in the ApoE4 non-carrier group] but interpreted the presentation as having massaged the data."

101. Following ICAD, the Companies held a joint investor conference call in the evening (the "July 29, 2008 Conference Call") to discuss the Phase II results, during which additional, negative information was disclosed, including more information on the fact that some AAB-001 recipients developed brain bleeds. Specifically:

> Tim Anderson (Sanford C. Bernstein & Company Analyst):
>
> The company press release doesn't mention bleeding episodes, yet a press interview with someone in clinical development at Wyeth says there were three or four bleeds, which seems like it could be important, given how the drug works. I'm hoping you could characterize those patients better in terms of two things, ApoE4 carrier status and also the dose of drug that they received.
>
> Ron Black (Wyeth Research, Assistant Vice President, Neuroscience):
>
> Sure. I think when we talk about bleeding in particular, we need to distinguish what we're talking about here in this population. . . . In this case, we saw some of these microbleeds in patients with vasogenic edema. There were three of the patients out of the 12 with vasogenic edema who had these tiny little areas of microbleeding. . .

102. Not surprisingly, Wyeth's stock price fell dramatically once investors learned for the first time about the true limits of AAB-001's efficacy, its many troublesome side effects, and the complete lack of dose response. JP Morgan analyst Chris Schott concluded: "We believe that today's results leave unanswered questions about the efficacy profile of [AAB-001]."

Another analyst stated, "[E]nough information was revealed to suggest that the Phase [II] results could be completely invalid." Wyeth's stock price declined from $45.11 to $ 39.74 – an 11.9% decrease, which amounted to the largest single day drop in six years of trading – on extremely heavy volume of over 55 million shares. In this one trading day, Wyeth's market capitalization declined by over $7 billion.

103. Also on July 29, 2008, financial reporter David P. Hamilton from *CBS BusinessWatch* published an article entitled "Wyeth, Elan and Bapineuzumab – How to Lie With (Drug) Statistics," which summarized Wyeth's actions as follows:

> In what is becoming a sadly common ritual, Wyeth and Elan are pressing forward with an expensive, large-scale "phase III" trial of a risky drug based on wishful thinking and shoddy statistical analysis.
>
> * * *
>
> Earlier today, Wyeth and Elan disclosed detailed results of the drugs phase II trial, which found that bapineuzumab failed to improve cognitive function in a test of 234 Alzheimer's patients after 18 months of treatment. You could be forgiven for not gleaning that from the companies' joint press release, however, as Wyeth and Elan chose instead to highlight post-hoc analyses that purported to demonstrate the drug's efficacy in a subset of patients who don't have a gene variant called ApoE4, which increases the risk of Alzheimer's.
>
> To put it bluntly, this is magical thinking on a truly impressive scale. A few points:
>
> - Prospective measures of success are the only accurate way to judge trial results. Honest clinical trials require researchers to specify in advance what they're looking for — and by that measure, the bapineuzumab trial was a failure.
>
> - Post-hoc subgroup analyses amount to lying with statistics. By contrast, a post-hoc analysis involves mining the trial data in order to identify some group of patients who appeared to benefit from the drug. It's tantamount to moving the finish line after the race is over — or, as FDA's Richard Pazdur memorably put it, firing an arrow into the wall and then drawing a target around it.
>
> - Such findings in subgroups rarely hold up under further study. Or, as the old computer-science saying goes, "Garbage in, garbage out."

- Drug companies will do and say almost anything to boost the promise of a potential blockbuster. Wyeth and Elan don't expect data from the phase III trial in patients without the ApoE4 gene variant until 2010. A lot can happen in that time, including the possibility that the FDA will once again warm to the idea of approving drugs based on marginal evidence.

It's like the old story in which a prisoner staves off execution by promising to teach the king's horse to sing within a year, reasoning: "A year is a long time. The king might die. The horse might die. I might die. And maybe the horse will learn to sing."

Without doubt, there's a huge need for effective Alzheimer's treatments. But companies like Wyeth and Elan do themselves — and patients — no favors by torturing their data and hyping all-but-meaningless results this way.

104. Upon the disclosure of the full Phase II results on July 29, 2008, including numerous other shortcomings and limitations of AAB-001 previously withheld that were dramatically at odds with the Companies' public statements touting the "spectacular," "strong" and "very meaningful" nature of the Phase II Interim Results, the price of Wyeth's stock fell dramatically. Based on the July 29, 2008 full release of the Phase II results, numerous, once-hopeful researchers and scientists immediately began to question the underpinning of the beta amyloid hypothesis, including one who was quoted in Forbes as stating that AIP's Phase II results put the hypothesis "in a meltdown."

## VI. POST-CLASS PERIOD ANALYSIS AND EVENTS CONCERNING AAB-001

105. AAB-001 remains unapproved by the FDA and its ongoing Phase III testing throughout the United States and Europe is plagued by setbacks. For example, in October 2008, the Company disclosed that lingering doubts set in motion by the revelation of the truth regarding AAB-001's Phase II results were resulting in Phase III delays. The following exchange occurred on an October 22, 2008 investor conference call:

David Risinger (Merrill Lynch Analyst):

You had mentioned that with respect to bapineuzumab in Europe, you're engaging in meetings with Regulatory Authorities before they permit enrollment and/or permit continued dosing. Can you explain what changed to slow enrollment relative to your original expectation several months ago . . .

Mahady:

***With the information that broke with the Phase II data and publicity around it, in the ensuing weeks and months we began to get requests from individual countries to review the full Phase II data, to review the Phase III protocols, any protocol amendments that had been implemented and that has been going on for the past few weeks.*** As a consequence, in places where and in many places we had yet to begin enrollment they had ***asked that that enrollment not begin until they completed that review and a couple of countries where enrollment had just begin, they asked us to hold until they finish this review.*** Those meetings and those submissions are ongoing as we speak and hope to have better understanding of where we are but I think your insight is correct. We really are a little behind where we would like to be in getting the full European program up and running. (emphasis added)

106. On April 9, 2009, Elan and Wyeth announced further set backs in Phase III testing. In their joint Press Release, entitled "Elan and Wyeth Plan to Amend Bapineuzumab Phase III Protocols," the Companies stated the Safety Monitoring Committee that was overseeing the trial made the decision to discontinue testing at the higher 2.0 mg/kg doses "following its review of vasogenic edema (VE) in the ongoing Phase 3 clinical program." In other words, the most troubling side effect of AAB-001, which was down played by the Companies in early Phase II testing to help justify the push to move to Phase III, was again proving to be an intolerable risk for patients willing to undergo this experimental treatment.

107. Johnson & Johnson took over Elan's half of the development of AAB-001 when it bought Elan's Alzheimer's program in late 2009. Pfizer, as a result of its acquisition of Wyeth in October 2009, now controls the other half of the program. The Phase III study results for AAB-001 were originally forecast for release in 2010, based on Wyeth's prior announcement that recruitment for the first Phase III, 18-month study of the drug was completed at the end of 2008.

According to Johnson & Johnson officials, it now appears that study results for AAB-001 may not yield results until 2012 or 2013 because Johnson & Johnson and Pfizer are continuing to add patients to the study. On May 11, 2010, the *Los Angeles Times* reported that current Pfizer Vice President, Dr. Steve Romano, declined to speculate on the timing of a potential submission to the FDA.

## VII. DEFENDANTS ACTED WITH SCIENTER

### A. DEFENDANTS' ACTUAL KNOWLEDGE OF THE NEGATIVE PHASE II INTERIM RESULTS

108. During the Class Period, Defendants had actual knowledge of the misleading nature of the statements they made. Throughout the Class Period, Defendants were aware of the interim review and final Phase II study results. Defendants participated in a scheme to defraud and engaged in acts, practices, and a course of business that operated as a fraud or deceit on purchasers of Wyeth common stock during the Class Period.

109. Defendants were fully aware of the interim review and final results of the Phase II trial, and they knew the results of the Phase II were abysmal, because they conducted the study and admittedly reviewed the interim data by at least May 2007, prior to disclosing that Wyeth would move forward with Phase III testing. Defendants stated that they would conduct, and did conduct, an interim review of Phase II Interim Results in the Spring of 2007, based on very specific criteria, and after they did so, they assured analysts and investors that they had reviewed and were familiar with the Phase II study results. Defendants knew the results of the Phase II trial, as the study was completed in March or April 2008.

110. The CW is a former Wyeth Executive and member of both the Company's Neuroscience Steering Committee and Bapineuzumab Steering Committee. He/she was employed by Wyeth from approximately 2005 until the end of 2008. The CW *personally viewed*

*the Phase II Interim Results*, and states that the Phase II Interim Results were not "spectacular" or "strong" in any sense of the words. Nor did they meet the predetermined "very specific criteria" that the Companies claimed were necessary in order for the Companies to move forward with Phase III trials. According to the CW, the Phase 2 Interim Results – which at least Ruffolo and other high-ranking Wyeth executives received and reviewed – demonstrated, at best, circumstantial evidence of efficacy, which was only possible to detect after the Companies had abandoned the predetermined criteria of Phase II testing and conducted *post-hoc* analyses that spun the data in the Companies' favor with respect to one sub-group of patients.

111. According to the CW, Wyeth had an Executive Steering Committee ("ESC") related to AAB-001, which was comprised of Defendant Ruffolo; Hilary Malone ("Malone"), a Senior Vice President and Head of Regulatory Affairs; Gary Stiles ("Stiles"), the former Wyeth Chief Medical Officer, Clinical Research; Bruce Schneider ("Schneider"), Head of Project Management and a trained statistician; Thorir Bjornsson ("Bjornsson"), Wyeth's former Head of Clinical Pharmacology; and, possibly, Camardo. Bjornsson and Camardo reported to Stiles. Stiles reported to Ruffolo. Ruffolo co-chaired the ESC with his counter-part at Elan, and reported directly to Wyeth's CEO, which at the time of the Phase II Interim Results review was Defendant Essner.

112. During a private meeting soon after Defendant Ruffolo and others decided to move forward with Phase III testing, one of the CW's superiors showed him the Phase II Interim Results because he was "pissed off" that Wyeth, at the urging of Ruffolo, decided to proceed with a massive Phase III study. According to the CW and his superior, the decision was both aggressive and premature given the data from the Phase II Interim Results. The Phase II Interim Results showed only circumstantial evidence of efficacy that, according to the CW, only became

"interesting" or "encouraging" when the population was divided into sub-groups according to whether the patient was positive or negative carrier of the ApoE4 gene. According to the CW and his superior, while additional Phase II testing of this sub-group could be considered "interesting" and warranted further investigation, it justified only a Phase II "exploratory" trial, not the large scale Phase III "confirmatory" trial Wyeth chose to undertake. The CW reported that the AAB-001 team ultimately succumbed to Ruffolo's aggressive nature in pushing through the development of AAB-001 into Phase III testing.

113. Additionally, according to the CW, there was no significant difference between the interim data and the final AAB-001 Phase II results. Therefore, Wyeth was fully aware at the time of its decision to move the Phase III that the initial interim data or "sneak peak" could not and did not meet the predetermined end points necessary to move to Phase III, which were announced to the market.

114. Further, the Individual Defendants were all aware of the Phase II Interim Results preliminary data because AAB-001 was one of Wyeth's most important and promising pipeline drugs. Any rational, prudent executive would keep a close eye on any developments with AAB-001, which Defendants' themselves portrayed as presenting an opportunity for "transformational growth" of the Company. This is particularly so with respect to developments, like the Phase II Interim Results review, which led to the initiation of an expensive Phase III study that cleared a path for regulatory approval.

115. The Defendants' scienter is also evident because of the deliberate distortion of the true results of the Phase II study. Knowing that the Phase II Interim Results and final results were abysmal – failing all efficacy and safety endpoints by a large measure – the Defendants conspired to hide the truth through a supposed "post-hoc analysis" which abandoned the Phase II original

protocols. The Defendants tortured, mined, and spun the data of the Phase II trial until they could declare it a success.

### B. DEFENDANTS HAD STRONG MOTIVES AND INCENTIVES TO MISLEAD WYETH'S INVESTORS

116. Defendants were highly motivated to conceal, and did conceal, these Phase II results from the public for as long as possible. As analysts and investors digested Wyeth's decision to proceed to Phase III testing, Wyeth's stock price was on the rise – a feat Wyeth had struggled to achieve for quite some time. The 5/21/2007 Announcement of Wyeth's decision to move forward with Phase III testing drove Wyeth's stock price above $58 per share, a level Wyeth had not seen since May 2002.

117. A positive market perception of AAB-001 was thus critically important to Wyeth at the time. Wyeth's stock price had languished for years in the wake of diet drug litigation, patent threats and pressures on Effexor and Protonix, and failed New Drug Applications with bazedoxifene (osteoporosis), bifeprunox (schizophrenia), and Pristiq (menopause).

118. With Wyeth's stock price finally on the rise, largely based on the false promise of AAB-001 due to the move into Phase III testing, certain executive officer defendants, including Defendants Ruffolo and Martin exercised and sold valuable stock options while material adverse information about the Phase II Interim Results remained concealed from the market. Indeed Ruffolo's and Martin's highly suspicious insider trading was perfectly timed with the release of false and misleading AAB-001 news, strongly suggesting that each had knowledge that the Phase II results were a failure and that the public release of their decision to move to Phase III testing had inflated the market for Wyeth's shares. In this regard, on May 21, 2007, the Company announced the move to Phase III testing, signaling to the market that the Phase II interim peek at the data was strong and spectacular. *The very next day*, when the price of Wyeth stock jumped

4% on the bullish AAB-001 news to trade at a Class Period high of over $58 per share, both Ruffolo and Martin exercised options and in same day sales realized significant personal gains.

119. Specifically, on May 22, 2007, Ruffolo exercised options and sold 130,436 Wyeth shares, at $58.33 per share, for a net gain of $2,360,109.

120. Martin sold 200,500 shares at $57.97 per share on May 22, 2007, for a net gain of $283,347.30. The sale included 88,000 shares from options exercised that were set to expire on April 27, 2010 with a conversion price of $56.5938 and 112,500 shares set to expire on April 26, 2011, with a conversion price of $56.525. If the results of the Phase II trials showed any signs of success or promise, Martin would have had little motivation to exercise such a large amount of options for such a marginal gain, when the options were not set to expire until 2010 and 2011.

121. Further, by May 22, 2007, Martin had exercised every profitable option available to him. On December 31, 2006 Martin had 600,702 exercisable options. By late April 2007, Martin had 515,536 options that were exercisable at strike prices of $56.5938 and below. By May 22, 2007, sold *all* 515,536 shares from his sales on April 25, 2007, April 27, 2007 and May 22, 2007. Additionally on June 13, 2007 – just before the release of the top-line results of Phase II – Martin sold his remaining 12,541 shares, at $57.15 per share and realized a net gain of $716,578 (for an aggregate personal financial windfall of $4,496,876).

122. Defendants were also powerfully motivated to conceal the Phase II Interim Results because it was critically important for them to enroll patients in the Phase III AAB-001 study as soon as possible. The Phase III trials required over 4,000 Alzheimer's patients willing to take a chance on an experimental drug. Disclosing the poor performance of AAB-001 in Phase II testing would have significantly impeded Phase III enrollment, and jeopardized or eliminated any chance for Wyeth to rush AAB-001 to market. Additionally, physicians would be much less likely to

enroll a patient into an experimental drug trial when prior trials showed little or no efficacy and/or serious safety concerns. Thus, Defendants concealed that AAB-001 had failed in the Phase II Interim Results review and led everyone to believe that the results of the review and the final results of Phase II testing were strong and spectacular.

123. Finally, Defendants were motivated to conceal and manipulate the Phase II Results so that AAB-001 could retain its all important "Fast Track" status. Under FDA guidelines, Fast Track status for drugs such as AAB-001 is retained only as long as the emerging clinical data concerning the drug continues to suggest it will address unmet medical needs. Fast Track status was of the utmost importance to Defendants because it meant getting AAB-001 to market sooner. Defendants were thus highly motivated to conceal the extremely disappointing data from the Phase II trial.

## VIII. LOSS CAUSATION

124. Lead Plaintiffs and the putative Class suffered substantial damages as a direct and proximate result of Defendants' fraudulent conduct as alleged herein.

125. During the Class Period, Defendants made or caused to be made a series of materially false and misleading statements about the AAB-001 Phase II study results. These material misstatements and omissions had the purpose and effect of creating in the market an unrealistically positive assessment of Wyeth and its business prospects as they related to the success of AAB-001, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Lead Plaintiffs purchasing the Company's common stock at artificially inflated prices. But for Defendants' misrepresentations and fraudulent acts, Lead Plaintiffs would not have purchased Wyeth common stock, or would not have purchased them at the artificially inflated prices at which they were offered during the Class Period.

126. Starting with the May 21, 2007 press release announcing the initiation of a Phase III clinical trial of AAB-001, Defendants mislead investors to believe that they had seen spectacular and very strong results in the Phase II trials, which satisfied very specific safety and efficacy parameters. The May 21 release announced that the decision to initiate Phase III clinical testing was based on the "totality of what the companies have learned from their immunotherapy programs, including a scheduled interim look at data from an ongoing Phase II study," explaining that the key end-points in the Phase II trial "include[d] ADAS-Cog (assesses cognition), Neuropsychological Test Battery (NTB) and DAD score (measures quality of life)." Thus, Defendants lead Plaintiffs to believe that the Phase II results, at least preliminarily, satisfied the ADAS-Cog and DAD tests.

127. As a direct result of the May 21, 2007 Announcement, Wyeth's stock shot up 4% in one day on heavy trading volume of over 28 million shares to close at $58.41, a share price not seen since May of 2002. By the following day, Wyeth common stock reached its Class Period high of $58.42.

128. Throughout the Class Period, Defendants continuously misrepresented the success of the Phase II study, the safety, efficacy and promise of AAB-001, and touted the high "transformational" growth potential that a Phase III drug like AAB-001 brought to investors in the near to mid-term. Such misrepresentations ensured that Wyeth's stock price remained artificially inflated.

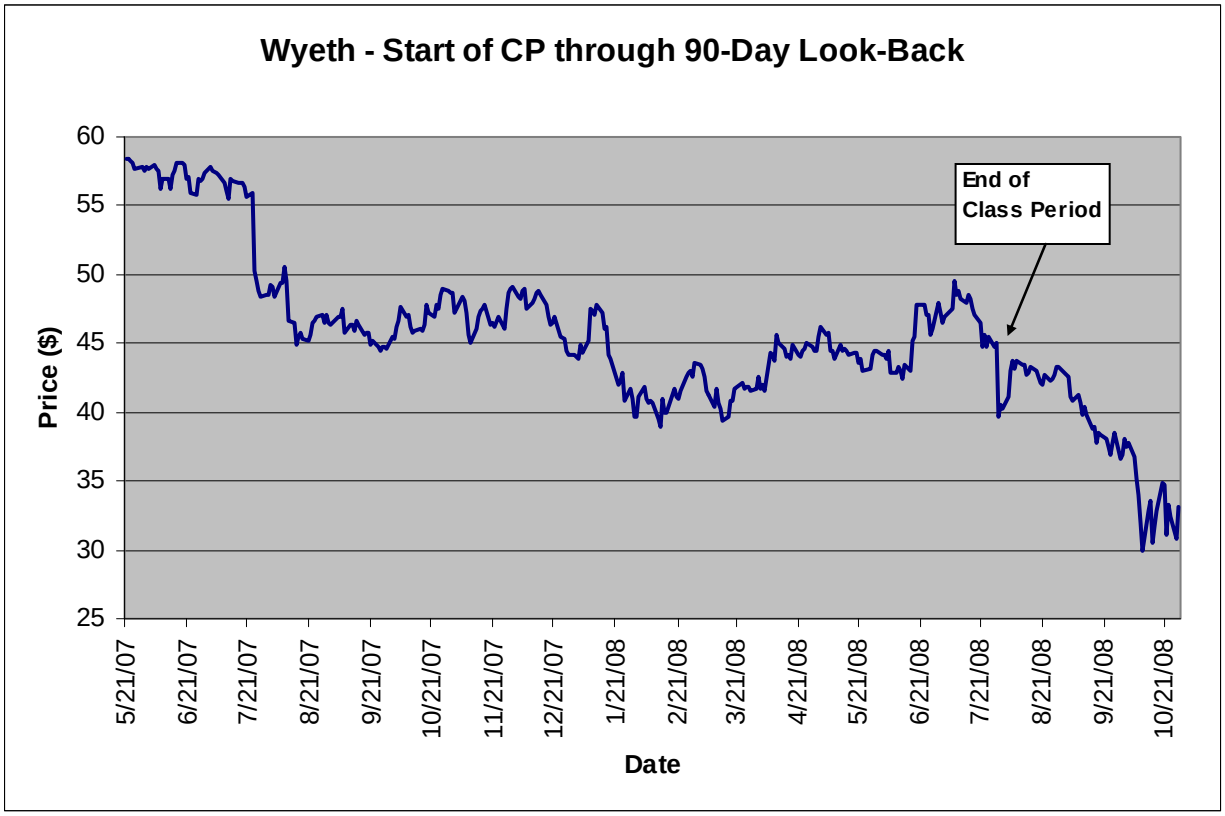
129. On June 17, 2008, Defendants revealed for the first time an abridged and highly spun version of the top-line Phase II results, which were scheduled to be released and presented about a month later. Like the May 21, 2007 Announcement, the June 17, 2008 release announced "encouraging" findings from the Phase II study of AAB-001, touting "statistically significant and

clinically meaningful benefits in important subgroups." The June 17, 2008 Announcement stated that Phase II testing showed that AAB-001 "appeared to have clinical activity in treating Alzheimer's disease." The Announcement further stated that the Phase II preliminary analysis provided "continued validation" for AAB-001's mechanism of action, which was an "important milestone" to bring this new treatment option to patients. According to the companies, the Phase II preliminary results "clinically support our decision to move into Phase 3 last year." The June 17 release also emphasized that the pre-specified efficacy endpoints for the study were "change from baseline in ADAS-cog and DAD in [the 3 dose groups] against their placebo cohorts."

130. The investment community understood the June 17, 2008 Announcement to mean that AAB-001 had outperformed the placebo in a sub-group of patients using the ADAS-cog and DAD tests, among others. Indeed, Guillaume van Renterghem, an analyst at Canaccord Adams stated, in response to the June 17, 2008 Announcement, "[t]he results are very good, especially surprising was the ADAS-cog analysis, which is the gold standard endpoint. Also the NTB outcome is important as this is the primary endpoint for the Phase 3 trial." In the days immediately following the June 17, 2008 Announcement, and as a direct result of the announcement of the purported success of AAB-001, Wyeth's stock rose 10% (approximately $5).

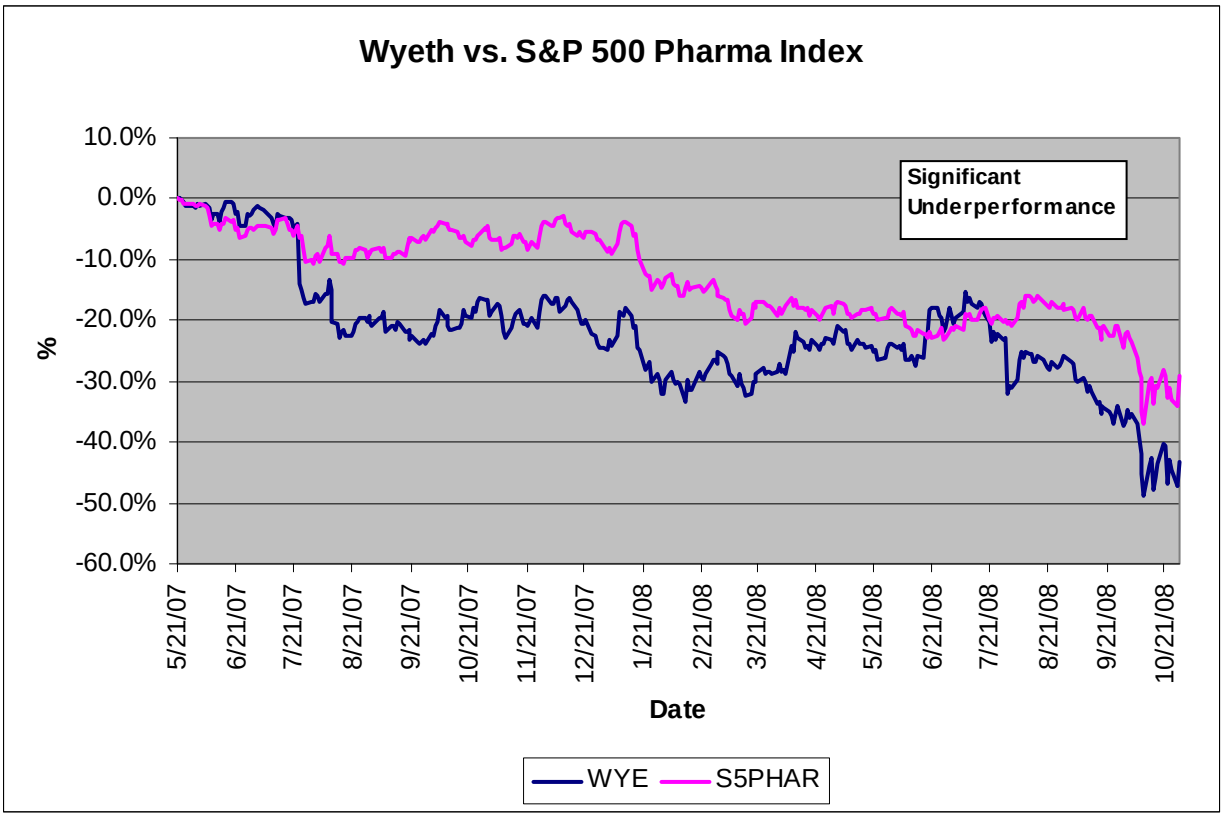
131. The full Phase II study results for AAB-001 were finally disclosed on July 29, 2008, at a widely attended medical conference. At the conference, investors, for the first time, learned the true limits of AAB-001's efficacy, its many troublesome side effects, and the complete lack of dose response. In response to this news, Wyeth's stock price experienced its largest single-day drop in six years of trading, falling nearly 12% in one day from $45.11 to $39.74 per

share on extremely heavy volume of over 55 million shares. Wyeth's shareholders lost over $7 billion in equity.




132. In total, from its Class Period high of $58.42 per share on May 22, 2008, Wyeth's share price declined $18.68 per share, or 32%.

133. The decline in Wyeth's stock price at the end of July 2008 can not be attributed to an industry-wide downturn. A snapshot of Wyeth's historical stock price chart during the relevant period, compared to Large Cap Pharma Index chart, shows that the Large Cap Pharma Index generally was on the rise in July 2008, when Wyeth's July 29, 2008 release and presentation of the full Phase II data caused its stock price to collapse. The historical price charts for Wyeth and the Large Cap Pharma Index are set forth below to illustrate these divergent price paths in July 2008.




## IX. CLASS ACTION ALLEGATIONS

134. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Wyeth publicly traded common stock during the Class Period May 21, 2007 through and including July 29, 2008 (the "Class"). Excluded from the Class are (a) Defendants; (b) members of the immediate families of the Individual Defendants; (c) any subsidiaries of Defendants; (d) any affiliate, as that term is defined by the federal securities laws, of Wyeth, Pfizer or any other defendant, including the 401(k) plans of Wyeth and Pfizer; (e) any person or entity who is a partner, executive officer, director or controlling person of Wyeth (including any of their subsidiaries or affiliates) or any other Defendant; (f) any entity in which any Defendant has a controlling interest; (g) Defendants' directors' and officers' liability insurance carriers, and

any affiliates or subsidiaries thereof; and (h) the legal representative, heirs, successors and assigns of any such excluded party.

135. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Wyeth had approximately 1.35 billion shares of common stock outstanding, owned by thousands of persons, with an average daily trading volume in excess of 1 million shares during the Class Period.

136. There is a well-defined commonality in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

a. whether the 1934 Act was violated by Defendants;

b. whether Defendants omitted and/or misrepresented material facts;

c. whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. whether Defendants knew or deliberately disregarded that their statements were false and misleading;

e. whether the prices of Wyeth's publicly traded common stock were artificially inflated; and

f. the extent of damage sustained by Class members and the appropriate measure of damages.

137. Lead Plaintiffs' claims are typical of those of the Class because Lead Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

138. Lead Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Lead Plaintiffs have no interests that conflict with those of the Class.

139. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

## X. PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

140. At all relevant times, the market for Wyeth common stock was an efficient market that promptly digested current information with respect to Wyeth from publicly available sources and reflected such information in the prices of Wyeth's shares, for the following reasons, among others:

a. Wyeth common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

b. As a regulated issuer, Wyeth filed periodic public reports with the SEC and the NYSE relating to its common stock;

c. Wyeth regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d. Wyeth was followed by dozens of securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

141. As a result of the foregoing, the market for Wyeth common stock promptly digested current information regarding Wyeth from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of Wyeth common stock suffered similar injury by trading in Wyeth common stock at artificially inflated prices and a presumption of reliance applies.

## XI. NO SAFE HARBOR

142. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Wyeth who knew that those statements were false when made.

## XII. CLAIMS FOR RELIEF

### COUNT 1

Violation of Section 10(B) of the Exchange Act and
Rule 10(B)-5 Promulgated Thereunder

(Against All Defendants)

143. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

144. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

145. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period. Defendants herein are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

146. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations, and future prospects of Wyeth, as specified herein. In particular, Defendants engaged and participated in a continuous course of conduct to conceal adverse material information regarding the ineffectiveness of, and safety concerns relating to, AAB-001 in Phase II testing.

Defendants concealed the negative Phase II results, thereby concealing the fact that AAB-001 missed all clinical endpoints, and thus completely failed the Phase II testing. In addition, Defendants concealed and further failed to disclose that AAB-001, as a result of Phase II testing, actually had demonstrated a negative impact on health due to serious safety issues encountered during the clinical study.

147. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct involving false and misleading statements, as specified herein, to mislead and defraud analysts, investors, and the public. In particular, Defendants made numerous affirmative misrepresentations during the Class Period, as specified above.

148. The allegations set forth above establish a strong inference that the Defendants acted with scienter throughout the Class Period in that they had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts. Defendants' material misrepresentations and/or omissions were done knowingly or with recklessness for the purpose and effect of concealing Wyeth's present and future business prospects from the investing public and supporting the artificially inflated price of Wyeth's common stock.

149. As a result of the Defendants' dissemination of the materially false and misleading information and failure to disclose material facts, as set forth herein, the Lead Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Wyeth common stock. Lead Plaintiffs and the Class would not have purchased Wyeth common stock at the prices they paid, would have paid less, or would not have purchased Wyeth common stock at all, if they had been aware that the market prices had been

artificially and falsely inflated by Defendants' fraudulent scheme, misleading statements, and material omissions.

150. At the time of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth herein, the Lead Plaintiffs and the Class were ignorant of the falsity of the statements and were ignorant of the omissions.

151. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the Class suffered economic damages in connection with their purchases of Wyeth common stock during the Class Period when the truth was disclosed, causing the value of Wyeth's common stock to decline dramatically.

**COUNT 2**

Violation Of Section 20(a) Of The Exchange Act

(Against The Individual Defendants )

152. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

153. During the Class Period, Defendant Essner, by virtue of his senior executive positions in Wyeth, including CEO, President and Chairman of the Board, was privy to confidential and proprietary information concerning Wyeth, its operations, finances, financial condition, and present and future business prospects relating to AAB-001. Essner had access to materially adverse non-public information concerning AAB-001. Because of his positions within Wyeth, Essner had access to non-public information about its business; finances; products (including AAB-001); markets; and present and future business prospects via access to internal corporate documents, conversations, connections with other corporate officers and employees, attendance at management and board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of his

possession of such information, Essner knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

154. Essner was a "controlling person" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of his positions of control, Essner was able to and did, directly or indirectly, control the conduct of Wyeth's business and its market disclosures.

155. Essner, because of his positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases, and presentations to securities analysts and through them, to the investing public. Essner was provided with copies of the Company's reports, press releases, advertisements, and marketing materials alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, Essner had the opportunity to commit the fraudulent acts alleged herein.

156. As a senior executive and controlling person of a publicly traded company whose stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NYSE and governed by the federal securities laws, Essner had a duty to promptly disseminate accurate and truthful information with respect to Wyeth's financial condition and performance, growth, operations, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Wyeth's common stock would be based upon truthful and accurate information. Essner's misrepresentations, omissions and course of conduct during the Class Period violated these specific requirements and obligations.

157. During the Class Period, Defendant Poussot, by virtue of his senior executive positions in Wyeth, including (at various relevant times) CEO, COO, President, Vice Chairman and Chairman of the Board, was privy to confidential and proprietary information concerning Wyeth, its operations, finances, financial condition, and present and future business prospects relating to AAB-001. Poussot had access to materially adverse non-public information concerning AAB-001. Because of his positions within Wyeth, Poussot had access to non-public information about its business; finances; products (including AAB-001); markets; and present and future business prospects via access to internal corporate documents, conversations, connections with other corporate officers and employees, attendance at management and board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of his possession of such information, Poussot knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

158. Poussot was a "controlling person" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of his positions of control, Poussot was able to and did, directly or indirectly, control the conduct of Wyeth's business and its market disclosures.

159. Poussot, because of his positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases, and presentations to securities analysts and through them, to the investing public. Poussot was provided with copies of the Company's reports, press releases, advertisements, and marketing materials alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent

their issuance or cause them to be corrected. Thus, Poussot had the opportunity to commit the fraudulent acts alleged herein.

160. As a senior executive and controlling person of a publicly traded company whose stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NYSE and governed by the federal securities laws, Poussot had a duty to promptly disseminate accurate and truthful information with respect to Wyeth's financial condition and performance, growth, operations, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Wyeth's common stock would be based upon truthful and accurate information. Poussot's misrepresentations, omissions and course of conduct during the Class Period violated these specific requirements and obligations.

161. During the Class Period, Defendant Martin, by virtue of his senior executive positions in Wyeth, including CFO and Vice Chairman of the Board, was privy to confidential and proprietary information concerning Wyeth, its operations, finances, financial condition, and present and future business prospects relating to AAB-001. Martin had access to materially adverse non-public information concerning AAB-001. Because of his positions within Wyeth, Martin had access to non-public information about its business; finances; products (including AAB-001); markets; and present and future business prospects via access to internal corporate documents, conversations, connections with other corporate officers and employees, attendance at management and board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of his possession of such information, Martin knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

162. Martin was a "controlling person" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of his positions of control, Martin was able to and did, directly or indirectly, control the conduct of Wyeth's business and its market disclosures.

163. Martin, because of his positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases, and presentations to securities analysts and through them, to the investing public. Martin was provided with copies of the Company's reports, press releases, advertisements, and marketing materials alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, Martin had the opportunity to commit the fraudulent acts alleged herein.

164. As a senior executive and controlling person of a publicly traded company whose stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NYSE and governed by the federal securities laws, Martin had a duty to promptly disseminate accurate and truthful information with respect to Wyeth's financial condition and performance, growth, operations, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Wyeth's common stock would be based upon truthful and accurate information. Martin's misrepresentations, omissions and course of conduct during the Class Period violated these specific requirements and obligations.

165. During the Class Period, Defendant Ruffolo, by virtue of his senior executive positions in Wyeth, including President, Wyeth Research, and Senior Vice President, Wyeth, was privy to confidential and proprietary information concerning Wyeth, its operations, finances,

financial condition, and present and future business prospects relating to AAB-001. Ruffolo had access to materially adverse non-public information concerning AAB-001. Because of his positions within Wyeth, Ruffolo had access to non-public information about its business; finances; products (including AAB-001); markets; and present and future business prospects via access to internal corporate documents, conversations, connections with other corporate officers and employees, attendance at management and board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of his possession of such information, Ruffolo knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

166. Ruffolo was a "controlling person" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of his positions of control, Ruffolo was able to and did, directly or indirectly, control the conduct of Wyeth's business and its market disclosures.

167. Ruffolo, because of his positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases, and presentations to securities analysts and through them, to the investing public. Ruffolo was provided with copies of the Company's reports, press releases, advertisements, and marketing materials alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, Ruffolo had the opportunity to commit the fraudulent acts alleged herein.

168. As a senior executive and controlling person of a publicly traded company whose stock was registered with the SEC pursuant to the Exchange Act, and was traded on the NYSE and governed by the federal securities laws, Ruffolo had a duty to promptly disseminate accurate

and truthful information with respect to Wyeth's financial condition and performance, growth, operations, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Wyeth's common stock would be based upon truthful and accurate information. Ruffolo's misrepresentations, omissions and course of conduct during the Class Period violated these specific requirements and obligations.

169. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Wyeth's common stock by disseminating materially false and misleading statements and/or concealing material adverse facts concerning AAB-001. The scheme: (i) deceived the investing public regarding the interim and final results of Phase II clinical testing of AAB-001, its failure to show a medically advantageous effect, and the business, operations and management and intrinsic value of Wyeth's common stock; and (ii) caused Plaintiffs and members of the Class to purchase Wyeth's common stock at artificially inflated prices, which declined dramatically when the truth was disclosed.

170. As set forth above, the Individual Defendants and Wyeth each violated Section 10(b) and Rule 10b-5 by their acts and omissions. By virtue of their positions as controlling persons, the Individual Defendants are liable under Section 20(a) of the Exchange Act.

171. As a direct and proximate result of Defendants wrongful conduct, Lead Plaintiffs and the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

**COUNT 3**

Violations Of Section 20A Of The Exchange Act

(Against Individual Defendants Ruffolo and Martin)

172. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

173. This Claim is asserted against Defendants Ruffolo and Martin (the "Section 20A Defendants"), and is based upon Section 20A of the Exchange Act, 15 U.S.C. § 78t-1, in connection with their insider trading in Wyeth common stock.

174. The Section 20A Defendants collectively sold nearly 331,000 shares of Wyeth common stock, reaping total net proceeds in excess of $2.5 million. Specifically, on May 22, 2007, Ruffolo sold 130,436 shares of Wyeth common stock for a net gain of $2,360,109 million; and Martin sold 200,500 shares of Wyeth common stock for a net gain of $283,347.

175. The Section 20A Defendants knowingly or with deliberate recklessness sold their Wyeth common stock during the Class Period while in possession of material, adverse, non-public information, including that the Phase II Interim Results were not spectacular or strong and that the Phase II Interim Results failed to achieve pre-specified, specific criteria (contrary to what the market had been told).

176. The Section 20A Defendants made such insider Wyeth stock sales contemporaneously with purchases of Wyeth common stock by Plaintiff Arca, which purchased 31,764 Wyeth shares on May 22, 2007, and 327 Wyeth shares on May 23, 2007. See Exhibit A to the Declaration of James E. Cecchi filed in support of the Motion to Appoint Lead Plaintiff and Lead Counsel by Security Police and Fire Professionals of America Retirement Fund (Dkt. No. 16-3).

177. By reason of Lead Plaintiff Arca's purchases of Wyeth stock contemporaneously with certain of the 20A Defendants' sales of Wyeth stock, Plaintiff Arca and Class members that, too, purchased Wyeth stock contemporaneously with the Section 20A Defendants' sales of same suffered recoverable damages. Under Section 20A of the Exchange Act, the Section 20A Defendants are liable to those Lead Plaintiffs for all profits gained and losses avoided by them as a result of these contemporaneous transactions.

178. As a direct and proximate result of the wrongful conduct alleged herein against Wyeth and the 20A Defendants, the Lead Plaintiffs and members of the Class have been damaged and, among other damages, seek disgorgement of the 20A Defendants profits, or losses avoided, on account of the insider transactions listed above.

## XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for relief and judgment in their favor, as follows:

(1) Determining that this action is a proper class action and certifying Lead Plaintiffs as class representative under Rule 23 of the Federal Rules of Civil Procedure and Lead Plaintiffs counsel as Lead Counsel;

(2) Awarding damages to Lead Plaintiffs and the Class pursuant to Section 10(b) of the Securities Exchange Act against all Defendants, jointly and severally, in an amount to be proven at trial;

(3) Awarding damages to Lead Plaintiffs and the Class pursuant to Section 20(a) of the Securities Exchange Act against Defendants Essner, Poussot, Martin, and Ruffolo;

(4) Awarding damages to Lead Plaintiffs and the Class pursuant to Section 20A of the Securities Exchange Act against Defendants Ruffolo and Martin;

(5) Awarding Lead Plaintiffs their reasonable costs and expenses incurred in this action, including a reasonable allowance of fees for Lead Plaintiffs' attorneys and experts; and Awarding Lead Plaintiffs and the Class such other and further relief as the Court may deem just and proper.

Dated: May 27, 2011

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO

By: /s/ James E. Cecchi
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ADDITIONAL PLAINTIFFS' COUNSEL

## CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically transmitted the foregoing CONSOLIDATED AMENDED COMPLAINT to the Clerk's office using the CM/ECF system for filing and transmittal of a notice of electronic filing to the CM/ECF registrants on record.

/s/ James E. Cecchi
JAMES E. CECCHI

Dated: May 27, 2011